James F. Hurst (*pro hac vice* forthcoming)
Diana M. Watral (*pro hac vice* forthcoming)
Ryan Moorman (*pro hac vice* forthcoming)
Robin McCue (*pro hac vice* forthcoming)
James R.P. Hileman (*pro hac vice* forthcoming)
KIRKLAND & ELLIS LLP
333 West Wolf Point Plaza
Chicago, Illinois 60654
Telephone: (312) 862-2000
james.hurst@kirkland.com
diana.watral@kirkland.com
ryan.moorman@kirkland.com
robin.mccue@kirkland.com
jhileman@kirkland.com

Yungmoon Chang (S.B.N. 311673)
KIRKLAND & ELLIS LLP
2049 Century Park East
Suite 3700
Los Angeles, California 90067
Telephone: (310) 552-4200
yungmoon.chang@kirkland.com

Additional Counsel Listed on Signature Page

Attorneys for Plaintiff
Eli Lilly and Company

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

ELI LILLY AND COMPANY,

Plaintiff,

v.

AIOS INC d/b/a FELLA HEALTH AND DELILAH, FELLA MEDICAL GROUP P.A., FELLA MEDICAL GROUP P.C.,

Defendants.

CASE NO. 3:25-cv-03535

COMPLAINT

DEMAND FOR JURY TRIAL

1. Aios Inc. (d/b/a Fella Health and Delilah) (separately "Fella Health" and "Delilah," collectively "Fella") is a telehealth company engaged in a conspiracy with doctor groups Fella Medical Group P.A. and Fella Medical Group P.C. (collectively "Fella Medical Group") to sell untested, unapproved weight loss drugs, diverting consumers from safe and effective medicines and risking patient safety.

2. Fella's scheme centers around tirzepatide, the active pharmaceutical ingredient in Plaintiff Eli Lilly and Company's ("Lilly") MOUNJARO® and ZEPBOUND®. Lilly's medicines, which have undergone 37 clinical trials, are the only FDA-approved tirzepatide medicines, and MOUNJARO® and ZEPBOUND® are approved only for under-the-skin injection and without additives like glycine or l-arginine.

3. Fella, by contrast, sells two forms of knockoff tirzepatide that have never been approved and have never been studied in clinical trials: oral tirzepatide, and tirzepatide mixed with additives called glycine and l-arginine. Fella's prescription, marketing, and sales of these knockoff drugs violate state law and the Lanham Act in several ways.

4. ***First***, Fella practices and controls the practice of medicine in violation of California state law. Fella directs all its patients to Fella Medical Group, which it describes as "independent medical groups." But they are far from independent: Non-physician Richie Cartwright—the founder and CEO of Fella—is also the CEO of Fella Medical Group P.A. and exercises control over Fella Medical Group P.C. Cartwright and other non-physician employees of Fella communicate directly with patients through social media, texts, and phone calls to directly provide patients with medical advice about how to use Fella's knockoff drugs. For instance, when a patient complained that Fella's untested knockoff drug was not working, Cartwright told the patient to take ***more*** of the knockoff drug faster, instructing the patient, "we'll just escalate your titration speed to ensure no wasted time." Fella also makes sweeping corporate decisions that dictate patient care, such as when Fella changed patients ***en masse*** from one tirzepatide formulation to another with additives.

5. ***Second***, Fella unfairly and deceptively markets and sells its oral and injectable tirzepatide as drugs that are safe, effective, and backed by science—when none of that is true. Fella cites to the results of Lilly's clinical trials in support of these claims. But Lilly's clinical trials did not evaluate oral

tirzepatide or tirzepatide combined with glycine or l-arginine, and Lilly is not aware of any clinical trials that have. Fella claims that its oral tirzepatide "dramatically reduce[s] hunger," provides "best-in-class weight loss," and "curbs appetite and cravings far greater than alternatives" all "without the hassle of injections." But Fella's oral tirzepatide has never been studied in clinical trials, much less evaluated by any regulatory authority for bioavailability, safety, or effectiveness. And even Fella's own employees admit when communicating with patients that its oral tirzepatide is "fairly ineffective," as reflected in their social media posts. Indeed, when confronted by customer insisting that is a "scam," a Fella employee said, "That's a fair point," because "they are less effective when compared to injectable format due to bioavailability." Similarly, Fella falsely, deceptively, and misleadingly tells patients its tirzepatide is personalized. In reality, Fella's tirzepatide drugs are mass-manufactured, one-size-fits-all products distributed to patients for no individualized purpose.

6. Lilly brings this action under California state law and the Lanham Act to stop Fella's improper corporate practice of medicine, unfair competition, deception, and false advertising, and Fella's conspiracy with Fella Medical Group that endangers patient safety.

THE PARTIES

7. Plaintiff Eli Lilly and Company is a corporation organized and existing under the laws of Indiana and has its principal place of business in Indiana.

8. Defendant Aios Inc. (d/b/a Fella Health and Delilah) is a Delaware corporation with a principal place of business at 2261 Market Street #4540, San Francisco, CA 94114. Both Fella Health and Delilah operate as telehealth platforms that focus on drugs for weight loss. Delilah is marketed towards women, and Fella Health is marketed towards men. Fella operates and conducts business in California, including by promoting and selling its tirzepatide products within the State.

9. Fella Medical Group P.A. is a Florida professional corporation with its principal place of business at the same location as Fella, 2261 Market Street #4540, San Francisco, CA 94114.

10. Fella Medical Group P.C. is a California professional corporation with its principal place of business at the same location as Fella, 2261 Market Street #4540, San Francisco, CA 94114.

JURISDICTION AND VENUE

11. The Court has subject matter jurisdiction over the Lanham Act cause of action pursuant to 15 U.S.C. § 1121 and 28 U.S.C. § 1331. The Court has supplemental jurisdiction over the state law cause of action pursuant to 28 U.S.C. § 1367(a), as it is part of the same case or controversy as the federal claim. Additionally, and in the alternative, this Court has subject matter jurisdiction on diversity grounds pursuant to 28 U.S.C. § 1332, as the parties are citizens of different states and the matter in controversy exceeds $75,000.

12. Fella is subject to personal jurisdiction in California because it has a principal place of business in the State of California where Fella recruits and employs California residents.[1] Fella is also subject to personal jurisdiction in California because it has significant contacts with the forum and has purposefully availed itself of the privilege of conducting business in California, including by operating and conducting business in California and by promoting and selling the tirzepatide products at issue in this Complaint into California and to California patients.

13. Fella Medical Group is subject to personal jurisdiction in California because it has a principal place of business located in the State of California. Fella Medical Group is also subject to personal jurisdiction because it has significant contacts with the forum and has purposefully availed itself of the privilege of conducting business in California.

14. Venue is proper in this District pursuant to 28 U.S.C. § 1391 because Fella, Fella Medical Group, and Cartwright reside and operate within the state and a substantial part of the events or omissions giving rise to Lilly's claim occurred in this District.

DIVISIONAL ASSIGNMENT

15. Pursuant to Civil L.R. 3-2(c), this case arises in the County of San Francisco, as a substantial part of the events or omissions giving rise to the claims occurred in the County of San Francisco. For example, Fella sells untested, unapproved weight loss drugs through its telehealth platform, which has a principal place of business at 2261 Market Street #4540, San Francisco, CA 94114.

[1] *See* LinkedIn, *Fella & Delilah Health*, https://www.linkedin.com/company/fella-delilah-health/ (last accessed on Apr. 11, 2025).

FACT ALLEGATIONS

I. LILLY'S TIRZEPATIDE INJECTABLE MEDICINES

A. Lilly's Long History of Developing and Manufacturing Safe and Effective Medicines

16. Lilly is an international medicine company and pharmaceutical manufacturer. Throughout its nearly 150-year existence, Lilly has pioneered countless life-changing discoveries. Today, Lilly's medicines help tens of millions of patients across the globe.

17. Lilly manufactures its medicines under strict controls in state-of-the-art facilities, which employ thousands of highly specialized personnel to ensure that Lilly's medicines meet its rigorous quality and safety standards. Transforming active pharmaceutical ingredients, or API, into medicine is a complex, methodical, and science-based process. Lilly follows Current Good Manufacturing Practices ("cGMP") across the design, monitoring, and control of manufacturing processes and facilities—from establishing robust quality management systems to obtaining quality raw materials and detecting and investigating product quality deviations. Each step—from chemical synthesis of the API to formulation, device assembly, and packaging—requires extensive testing and controls and specialized equipment.

18. Lilly develops and manufactures its medicines in compliance with FDA oversight, the international gold standard for pharmaceuticals. It includes rigorous pre-approval testing for safety and effectiveness under specific conditions for use, routine FDA inspections of manufacturing facilities, adverse event reporting obligations, and post-market surveillance and studies. Additionally, Lilly's medicines must be, and always are, accompanied by important labels, instructions, and warnings, which themselves are approved by FDA.

B. The Clinical Trial Process Necessary to Safely Bring Medicines to Market

19. Before a new prescription medication can be brought to market, it must be clinically tested through a rigorous series of studies designed to determine whether the medication is safe and effective for people to use and to receive FDA approval.[2]

[2] FDA, *The Drug Development Process - Step 3: Clinical Research* (Jan. 4, 2018), https://www.fda.gov/patients/drug-development-process/step-3-clinical-research#The_Investigational_New_Drug_Process; *see* 21 U.S.C. § 355(a).

20. FDA approval is famously hard to earn. More than 90% of drug candidates ultimately fail.[3] It is also an enormously costly and time-intensive process. "On average, it takes 10–15 years and costs $2.6 billion to develop one new medicine."[4]

21. To begin, drug sponsors first subject the drug candidate to preclinical testing to determine if the product is reasonably safe for initial use in humans and if the drug candidate exhibits pharmacological activity that justifies commercial development. Based on the data derived from preclinical testing, the drug sponsor is permitted to move the drug candidate into the clinical trial stage, in which it is tested in human subjects through a series of increasingly complex phases of studies, typically culminating in double-blind, multi-center, placebo-controlled clinical trials.

22. Phase I clinical trials typically evaluate the drug candidate's safety and generate data that will inform a range of doses that are safe for use in further clinical testing. This determination typically culls a large portion of drug candidates—for example, averaging across diseases, only 52% of drug candidates that make it through Phase I testing will progress to Phase II.[5]

23. Phase II trials are typically designed to preliminarily establish the effectiveness in addition to further confirming safety of the drug for a particular indication over a range of doses and to develop additional data on its safety. Another swath of drug candidates is eliminated in Phase II; drug candidates for various diseases that make it through Phase II only progress to Phase III at rates between 15% and 48.1% depending on disease type.[6] Phase III trials are designed to confirm the safety and effectiveness of a dose identified in Phase II trials in a much larger patient population as well as to monitor side effects.

24. Based on the data assembled during development in Phase I, Phase II, and Phase III clinical trials, a sponsor company can then submit a marketing application to FDA called a New Drug Application, where the sponsor requests that FDA approve the drug candidate for sale and marketing in the United States. The sponsor must detail every ingredient and component in its application to FDA.

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[3] Biotechnology Innovation Organization, *Clinical Development Success Rates and Contributing Factors 2011-2020* at 3 (Feb. 2021), https://tinyurl.com/bp5mb3xy (hereinafter "BIO 2021").

[4] PhRMA, *Research and Development Policy Framework* (Sept. 2024), https://tinyurl.com/5eecdtm9.

[5] BIO 2021, p. 7.

[6] *Id.*

25. Once approved for manufacture and distribution, FDA conducts inspections to monitor compliance with cGMP and reviews the drug's labeling to ensure appropriate disclosure of side effects, warnings, and contraindications. FDA also requires manufacturers to track and trace each finished product, to promptly report all adverse events, and to conduct further post-approval studies. All of this is to ensure that—in FDA's words—"American consumers benefit from having access to the safest and most advanced pharmaceutical system in the world."[7]

C. MOUNJARO® and ZEPBOUND®

26. FDA approved MOUNJARO® and ZEPBOUND® pursuant to Lilly's marketing application, which was the culmination of the lengthy and expensive clinical trial process described above that is designed to develop, study, and bring safe medicines to patients.

27. MOUNJARO® and ZEPBOUND® were approved after nearly a decade of development and have undergone testing in 37 clinical trials. They are two groundbreaking medicines containing a macromolecule Lilly discovered called tirzepatide. Tirzepatide targets patients' GLP-1 (glucagon-like peptide-1) and GIP (glucose-dependent insulinotropic polypeptide) receptors. Tirzepatide activates both receptors to improve blood sugar control and reduce appetite and food intake.

28. Both medicines meet critical patient needs. MOUNJARO® is FDA-approved to treat type 2 diabetes, and ZEPBOUND® is approved to treat chronic weight management and obstructive sleep apnea in certain adults. Today, Lilly manufactures, markets, and sells MOUNJARO® and ZEPBOUND® throughout the United States, among other places.

29. MOUNJARO® and ZEPBOUND® are the only FDA-approved medicines containing tirzepatide in the United States. Lilly's tirzepatide medicines are injectables; they are administered via under-the-skin injections. FDA has not approved, and Lilly does not sell, any tirzepatide product in oral form or with additives like glycine.

II. DRUG COMPOUNDING

30. Compounding is a "practice in which a licensed pharmacist, a licensed physician or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes

[7] FDA, *Development & Approval Process* (Aug. 8, 2022), https://www.fda.gov/drugs/development-approval-process-drugs.

or alters ingredients of a drug to create a medication tailored to the needs of an individual patient."[8] For example, if an individual patient is allergic to an ingredient in an FDA-approved medicine, a compounding pharmacy could produce a version of that medication that does not contain the allergen.

31. As FDA itself makes clear, "[c]ompounded drugs are not FDA-approved."[9] This means FDA does not review compounded drugs to evaluate their safety, effectiveness, or quality before they reach patients. Specifically, unlike FDA-approved medications, many compounded drugs are not clinically tested and are not reviewed or approved by FDA for safety and effectiveness. Further, many compounders are not subject to labeling requirements and need not comply with Current Good Manufacturing Practice regulations. Additionally, their facilities are not subject to inspections by regulatory authorities, and they have no reporting requirements for adverse events.

32. For these reasons, FDA has warned that "[c]ompounded drugs . . . do not have the same safety, quality, and effectiveness assurances as approved drugs. Unnecessary use of compounded drugs . . . exposes patients to potentially serious health risks."[10] Indeed, FDA recently reiterated that compounded drugs that purport to contain tirzepatide "have not undergone FDA premarket review for safety, effectiveness, and quality, and lack a premarket inspection and finding of manufacturing quality that is part of the drug approval process."[11]

33. Moreover, compounded drugs prepared at state-licensed pharmacies "are not subject to CGMP requirements and are subject to less robust production standards that provide less assurance of quality."[12]

34. As compounding of tirzepatide has become more prevalent, government agencies have warned the public as to the risks of such products. For instance, in July 2024, FDA sent a letter to compounding advocacy organizations warning that it has received "reports describing patients who

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[8] FDA, *Human Drug Compounding* (Dec. 18, 2024), https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding.

[9] FDA, *Compounding and the FDA: Questions and Answers* (Nov. 15, 2024), https://www.fda.gov/drugs/human-drug-compounding/compounding-and-fda-questions-and-answers.

[10] FDA, *Compounding and the FDA: Questions and Answers* (June 29, 2022), https://web.archive.org/web/20240803214713/https://www.fda.gov/drugs/human-drug-compounding/compounding-and-fda-questions-and-answers.

[11] Letter from Center for Drug Evaluation and Research, at 10 (Dec. 19, 2024), https://www.fda.gov/media/184606/download.

[12] *Id.*

experienced adverse events following the administration of compounded . . . tirzepatide."[13] Further, an October 2024 FDA statement warned of "multiple reports of adverse events, some requiring hospitalization, that may be related to dosing errors."[14]

35. Leading organizations, state governments, and foreign governments have also expressed concern. Thirty-eight state and territory Attorneys General and State Drug Task Forces have all warned the public about the dangers of these unsafe and unapproved products, including compounders using "non-sterile ingredients" and taking "no steps to sterilize them."[15] The Obesity Society, Obesity Action Coalition, and Obesity Medicine Association issued a joint statement regarding compounded GLP-1 medications, stating, "[u]nfortunately, many of the available alternatives [to GLP-1 therapies], like compounded versions of semaglutide and tirzepatide, are not what they are advertised to be."[16] The Pediatric Endocrine Society has also advised that "[c]linicians and patients [] should exercise caution when exploring options for non-brand name medications, particularly avoiding the use of non-FDA approved medications and those that come from non-FDA-approved compounding pharmacies."[17] Similarly, the JAMA Health Forum published a study that most websites selling compounded anti-obesity medications exclude important safety information and mislead consumers about the safety and effectiveness of their products.[18] Other patient and consumer groups have issued similar warnings,

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[13] Letter from Shannon Glueck, Branch Chief, FDA Compounding Branch 4, to Philip Dickison, CEO, Nat'l Council of State Boards of Nursing (July 16, 2024), https://www.pa.gov/content/dam/copapwp-pagov/en/dos/department-and-offices/bpoa/nursing/fda-safety-alert.pdf.

[14] FDA, *FDA's Concerns with Unapproved GLP-1 Drugs Used for Weight Loss* (Mar. 17, 2025), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/fdas-concerns-unapproved-glp-1-drugs-used-weight-loss.

[15] Nat'l Ass'n of Attorneys General, *State and Territory Attorneys General Urge FDA to Take Action Against Counterfeit and Illegally Sold GLP-1 Drugs*, (Feb. 19, 2025), https://www.naag.org/policy-letter/state-and-territory-attorneys-general-urge-fda-to-take-action-against-counterfeit-and-illegally-sold-glp-1-drugs/; FDA, *FDA warns patients and health care professionals not to use compounded drugs from Fullerton Wellness* (Nov. 1, 2024), https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-patients-and-health-care-professionals-not-use-compounded-drugs-fullerton-wellness.

[16] Obesity Medicine Ass'n, *Leading Obesity Expert Organizations Release Statement to Patients on Compounded GLP-1 Alternatives* (January 8, 2024), https://obesitymedicine.org/blog/leading-obesity-expert-organizations-release-statement-to-patients-on-glp-1-compounded-alternatives/ (Joint Statement On Compounded GLP-1 Alternatives) (last accessed Mar. 11, 2025).

[17] Pediatric Endocrine Society, *Statement on use of compounded semaglutide and other GLP-1 receptor agonists* (Jan. 16, 2024), https://pedsendo.org/drug-shortages/statement-on-use-of-compounded-semaglutide-and-other-glp-1-receptor-agonists/ (last accessed Mar. 11, 2025).

[18] Ashwin Chetty et al., *Online Advertising of Compounded Glucagon-Like Peptide-1 Receptor Agonists*, JAMA Health Forum (Jan 17, 2025), available at https://jamanetwork.com/journals/jama-health-forum/fullarticle/2829225 (last accessed Mar. 20, 2025).

including the National Consumers League and the American Diabetes Association, which recommended that patients avoid compounded products "due to uncertainty about their content, safety, quality, and effectiveness."[19]

36. The issue of unsafe compounded drugs purporting to contain tirzepatide has also received international attention. Australia recently banned the development and sale of compounded anti-obesity medications due to "increasing community concern" and "increasing reports of patients coming to harm from" compounded weight loss drugs.[20] The ban—effective October 2024—targets compounded drugs that are "being misrepresented and sold as replica [] Mounjaro®."[21] As Mark Butler, Australia's Minister for Health, said, "Australians should be able to have faith in the medications they use, including compounded medicines," and the ban "will protect Australians from harm and save lives."[22] Likewise, the South African government has proposed to prohibit the development of compounded GLP-1s. South Africa's regulatory authority has "noted with concern the number of compounded, substandard, and/or falsified versions" of tirzepatide products being sold to the public since "[t]he complexity of compounding GLP1 agonists, which are sterile medicines containing complex active substances[,] poses a public health and safety risk."[23]

III. CALIFORNIA PROTECTS PATIENTS FROM CORPORATIONS AND UNLICENSED INDIVIDUALS PRACTICING MEDICINE

37. Through an extensive statutory and regulatory regime, California protects patients by seeking to ensure that corporations run by non-physicians do not influence or control the practice of medicine. "The central tenet of CPOM is to protect physician autonomy . . . . This is especially important

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[19] Nat'l Consumers League, *NCL urges the public to heed warnings about unregulated versions of GLP-1 weight loss drugs* (Feb. 4, 2025), https://nclnet.org/the-national-consumers-league-urges-the-public-to-heed-warnings-about-unregulated-versions-of-glp-1-weight-loss-drugs/; American Diabetes Ass'n, *The American Diabetes Association Announces Statement on Compounded Incretin Products* (Dec. 2, 2024), https://diabetes.org/sites/default/files/2024-12/24.11.8%20compounding%20statement%20press%20release_FINAL.pdf.

[20] Department of Health and Aged Care, *Protecting Australians form unsafe compounding of replica weight loss products* (May 22, 2024), https://www.health.gov.au/ministers/the-hon-mark-butler-mp/media/protecting-australians-from-unsafe-compounding-of-replica-weight-loss-products (last accessed Mar. 20, 2025).

[21] *Id.*

[22] *Id.*

[23] South African Health Products Regulatory Authority, *SAHPRA's Position on GLP1 and GIP-GLP1 Products That Are Compounded, Substandard And Falsified* (Nov. 8, 2024), https://www.sahpra.org.za/news-and-updates/sahpras-position-on-glp1-and-gip-glp1-products-that-are-compounded-substandard-and-falsifiedas/ (last accessed Mar. 20, 2025).

when the fiduciary obligation of a corporation to its shareholders does not align with the physician's obligation to patients."[24]

38. In California, like in other states, unlicensed persons—both individuals and corporations—cannot own medical practices, or directly or indirectly employ physicians, or engage in the practice of medicine, Cal. Bus. & Prof. Code §§ 2400 *et seq.*, § 2052, and a corporation cannot hold a medical license, Cal. Bus. & Prof. Code § 2400. As the Medical Board of California ("the Board") recently made clear: "This section of the law is intended to prevent unlicensed persons from interfering with, or influencing, the physician's professional judgment."[25]

39. The Board has explained that certain decisions "should be made by a physician licensed in the State of California and would constitute the unlicensed practice of medicine if performed by an unlicensed person."[26] In particular, a licensed physician must have "[r]esponsibility for the ultimate overall care of the patient, including treatment options available to the patient."[27]

40. The Board has also made clear that the following decisions "should be made by a physician licensed in the State of California and would constitute the unlicensed practice of medicine if performed by an unlicensed person":

- Determining what diagnostic tests are appropriate for a particular condition;
- Determining the need for referrals to, or consultation with, another physician/specialist; and
- Responsibility for the ultimate overall care of the patient, including treatment options available to the patient.[28]

41. The Board also states that "the following 'business' or 'management' decisions and activities, resulting in control over the physician's practice of medicine, should be made by a licensed California physician and not by an unlicensed person or entity":

- Control of a patient's medical records, including determining the contents thereof; and

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[24] Jordan M. Warchol, *Corporate Practice of [Emergency] Medicine*, *in* Emergency Medicine Advocacy Handbook (5th ed. 2019), https://www.emra.org/books/advocacy-handbook/corporate-practice.

[25] Medical Board of California, "Physicians and Surgeons: Information Pertaining to the Practice of Medicine," https://www.mbc.ca.gov/Licensing/Physicians-and-Surgeons/Practice-Information/.

[26] *See* https://www.mbc.ca.gov/Licensing/Physicians-and-Surgeons/Practice-Information/.

[27] *Id.*

[28] *Id.*

- Selection, hiring/firing of physicians, health staff, and medical assistants.[29]

42. The California Business and Professions Code also prohibits the offer, delivery, receipt, or acceptance of consideration to induce the referral of patients, Cal. Bus. & Prof. Code § 650, and prohibits the use of unfair, unlawful, and/or fraudulent business acts or practices, *id.* §§ 17200 *et seq*. It also prohibits the making of untrue or misleading statements concerning professional or other services. *Id.* §§ 17500 *et seq.*

43. In addition to these prohibitions, California law also makes clear that a decision to alter the formulation, dosage, or titration schedule of a prescription drug cannot be made at a corporate level. Such decisions must be made by a physician pursuant to a good faith examination of the patient and upon the identification of a clinical need for the prescription. California Business & Professions Code § 2242 states that "[p]rescribing, dispensing, or furnishing dangerous drugs as defined in Section 4022 [*i.e.*, a prescription drug] without an appropriate prior examination and a medical indication[] constitutes unprofessional conduct." Cal. Bus. & Prof. Code § 2242. In addition, the healthcare professional is required to comply with "the appropriate standard of care." *Id.* That standard of care requires a "prior examination" ***and*** the identification of "a medical indication" showing that the prescription is warranted.

44. California's Business & Professions Code also imposes consent requirements on telehealth providers like Fella. California Business & Professions Code § 2290.5 states that "before the delivery of health care via telehealth, the health care provider initiating the use of telehealth shall inform the patient about the use of telehealth and obtain verbal or written consent from the patient for the use of telehealth as an acceptable mode of delivering health care services and public health. The consent shall be documented." Cal. Bus. & Prof. Code § 2290.5.

45. The Board further specifies that a physician is not permitted to operate a medical practice as a limited liability company, a limited liability partnership, or a general corporation.[30]

[29] *Id.*

[30] *Id.*

IV. FELLA'S UNLICENSED PRACTICE OF MEDICINE AND OTHER UNFAIR AND UNLAWFUL ACTS RELATED TO THE PRACTICE OF MEDICINE

46. Fella is engaged in the unlicensed practice of medicine on multiple fronts. Non-physicians at Fella offer unlicensed medical advice to patients. Fella also modifies prescriptions en masse without consulting with its patients and without any prior determination by a given patient's physician of any medical indication for doing so.

A. Fella and Fella Medical Group Are Controlled by Fella's Non-Physician Founder

47. Fella is a telehealth corporation that sells weight loss drugs to consumers, including compounded tirzepatide.[31] Richie Cartwright is the founder and CEO of Fella, and has an educational background in economics and statistics.[32] Cartwright does not have a medical degree and is not licensed to practice medicine in California or any other state.

48. Fella steers its patients to physicians at what it calls "independent medical groups."[33] Upon information and belief, Fella Medical Group is the only medical group that services Fella's patients. Fella's Membership Terms webpage specifies that customers will have a membership "with Fella Medical Group, P.A., a Florida professional medical corporation."[34]

49. Under California state law, unlicensed persons ***cannot*** own and control medical practices, Bus. & Prof. Code §§ 2400 *et seq.*, § 2052, or exercise undue control or influence over clinical decisions and doing so constitutes unfair competition.

50. Fella violates these prohibitions. Richie Cartwright, Fella's non-physician CEO and founder, exercises direct and indirect control and influence over Fella Medical Group.

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[31] Fella sources its injectable tirzepatide from Red Rock Pharmacy. It is unclear where it sources its oral tirzepatide.

[32] *See* LinkedIn, *Richie (Storm) Cartwright*, https://www.linkedin.com/in/richard-cartwright/ (last accessed on Apr. 11, 2025).

[33] Fella, *Terms of Use,* https://www.fellahealth.com/terms-of-use (last accessed on Apr. 11, 2025).

[34] Fella, *Membership Terms*, https://www.fellahealth.com/membership-terms (last accessed on Apr. 11, 2025).

B. Fella Engages in the Unlicensed Corporate Practice of Medicine by Controlling and Influencing Prescribing Decisions

51. Beyond Cartwright and Fella's control over Fella Medical Group, Fella also engages in the unlicensed corporate practice of medicine by allowing non-physicians to offer medical advice to customers and by modifying patient prescriptions for business reasons, not medical ones.

1. Fella's Non-Physicians Provide Medical Advice

52. Fella, through its officers and personnel, expressly and repeatedly provides customers with medical advice on social media and in text messages with customers—even though none of these business leaders have medical licenses in California or any other state. Each time, when a patient complains that Fella's knockoff tirzepatide is not working, Fella's officers and personnel respond by acting in the company's financial interest—giving the patient ***even more*** untested, unproven drugs. This violates California law.

53. Fella's founder Cartwright and employees Jordan Pellikan and Stanley Whitaker are particularly active in engaging with patients, among other employees. Cartwright responds to Fella customer comments and requests on Reddit under the username "Current-Lime."[35] Pellikan, the Head of Sales and Community and Program Lead at Fella, communicates with customers on Reddit under the username "These_Advertising_18."[36] Whitaker, Customer Success Lead at Fella, communicates with customers on Reddit under the username "Super-Stuff6819."[37]

54. Pellikan's educational background is in psychology,[38] and Whitaker's professional background is in sales and customer success.[39] Like Cartwright, neither have medical degrees, nor are they licensed to practice medicine in California or any other state.

55. Despite their lack of medical licensure, Cartwright, Whitaker, Pellikan, and other non-physician employees regularly and repeatedly engage directly with patients about their medical care on

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[35] Reddit, *Current-Lime*, https://www.reddit.com/user/Current-Lime/ (last accessed on Apr. 11, 2025).

[36] Reddit, *These_Advertising_18*, https://www.reddit.com/user/These_Advertising_18/ (last accessed on Apr. 11, 2025).

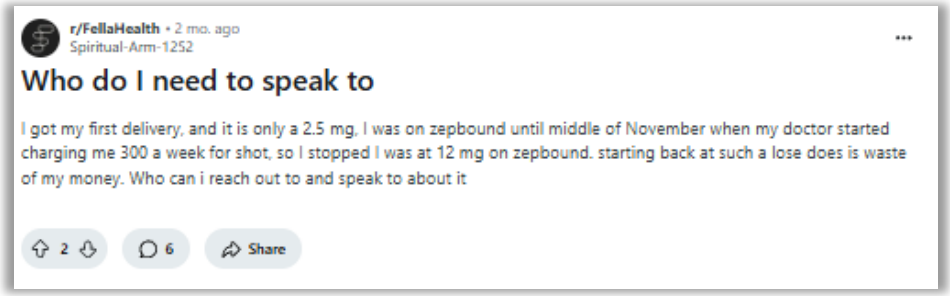
[37] Reddit, *Super-Stuff6819*, https://www.reddit.com/user/Super-Stuff6819/ (last accessed on Apr. 11, 2025).

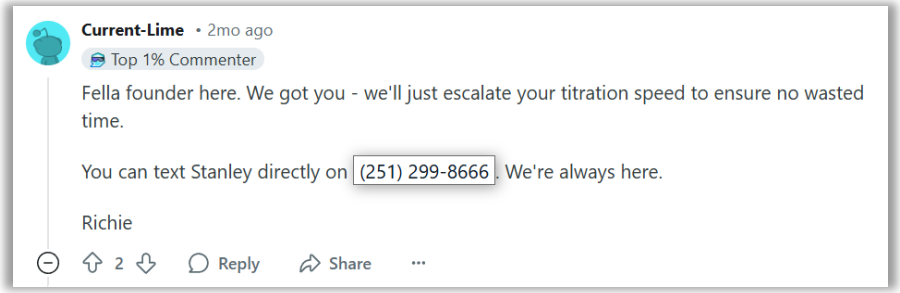
[38] LinkedIn, *Jordan Pellikan*, https://www.linkedin.com/in/jordan-pellikan-847023201/; Datanyze, *Fella Health*, https://www.datanyze.com/companies/fella-health/1312190304 (last accessed on Apr. 11, 2025).

[39] LinkedIn, *Stanley Whittaker*, https://www.linkedin.com/in/stanley-whittaker-6a145526/ (last accessed on Apr. 11, 2025).

Reddit and other social media, through at least public posts, direct messages, phone calls, and text messages.[40]

56. For example, in a recent Reddit post, a Fella customer asks who he could contact at the company to increase his dosage rate of Fella's knockoff drug that was not working, explaining "[2.5 mg] is a waste of my money."[41] Cartwright responds directly with medical advice about how to change the patient's dose: "We got you – we'll just escalate your titration speed to ensure no wasted time." Cartwright also tells the patient to "text Stanley" (*i.e.*, non-physician Whitaker).[42]





57. This exchange constitutes the practice of medicine—a practice for which Cartwright and Whitaker are unlicensed. Cartwright, who has no medical licensure, states that Fella will provide an accelerated titration schedule (*i.e.*, a dosage increase) for a prescription drug to a patient and refers him to Whitaker, a non-physician.

58. This is far from an isolated incident. Cartwright frequently tells customers that he can help increase their dosage amounts of Fella's knockoff drugs if they contact him or his non-physician customer

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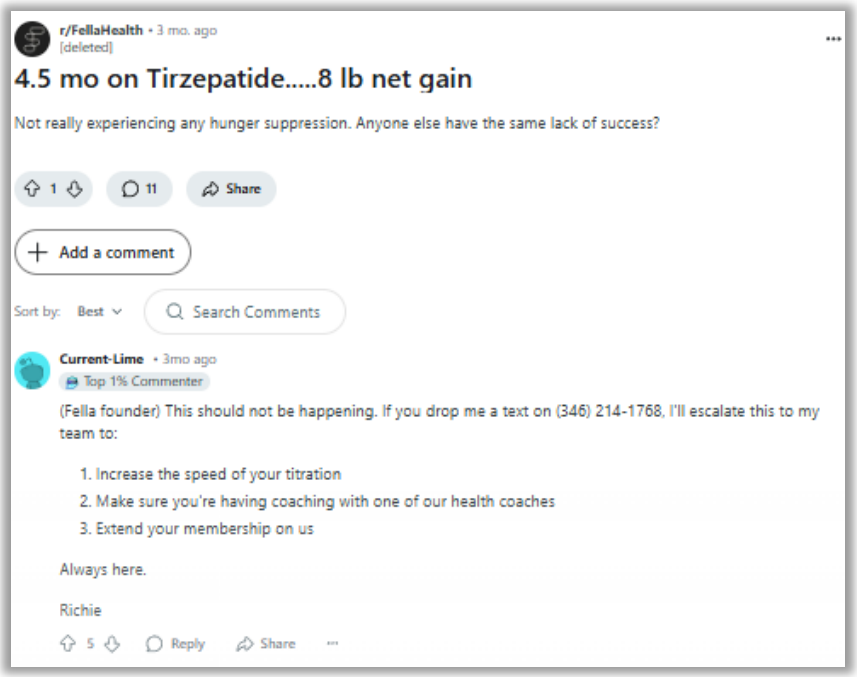
[40] Reddit, *Fella Health*, https://www.reddit.com/r/FellaHealth/. In dozens of posts on the Fella Health subreddit, Fella employees provide their personal contact numbers for consumers to reach out individually with questions and concerns. They are as follows: Richie Cartwright, (346) 214-1768; Stanley Whittaker, (251) 299-8666; Jordan Pellikan, (469) 949-1650.

[41] Reddit, *Who do I need to speak to,* (Feb. 5, 2025), https://www.reddit.com/r/FellaHealth/comments/1iihlxn/who_do_i_need_to_speak_to/?rdt=52050 (last accessed on Apr. 11, 2025).

[42] *Id.*

success team directly. For example, Cartwright told one customer who was "not really experiencing any hunger suppression" with Fella's knockoffs that he would help them "increase the speed of [their] titration[.]"[43]

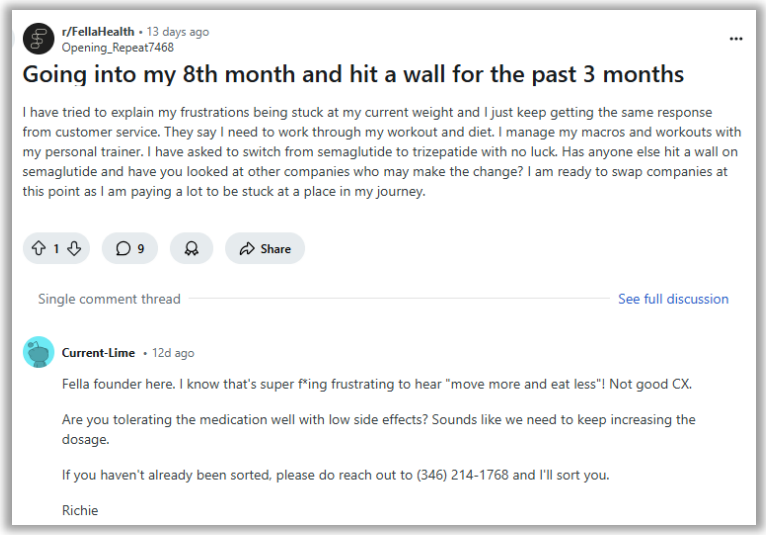


59. Another patient complains he "hit a wall" with Fella's knockoff drug—that is, Fella's knockoff was not working—and Cartwright again offers the same advice, this time also commenting on the patient's side-effect profile as well.[44] He says: "Are you tolerating the medication well with low side effects? Sounds like we need to keep increasing the dosage. If you haven't already been sorted, please do reach out to [Cartwright's personal number] and I'll sort you."[45]

[43] Reddit, *4.5 mo on Tirzepatide.....8 lb net gain*, (Jan. 15, 2025), https://www.reddit.com/r/FellaHealth/comments/1i28t1m/45_mo_on_tirzepatide8_lb_net_gain/ (last accessed on Apr. 11, 2025).

[44] Reddit, *Going into my 8th month and hit a wall for the past 3 months*, (Mar. 10, 2025), https://www.reddit.com/r/FellaHealth/comments/1j7rfpm/going_into_my_8th_month_and_hit_a_wall_for_the/ (last accessed on Apr. 11, 2025).

[45] *Id.*

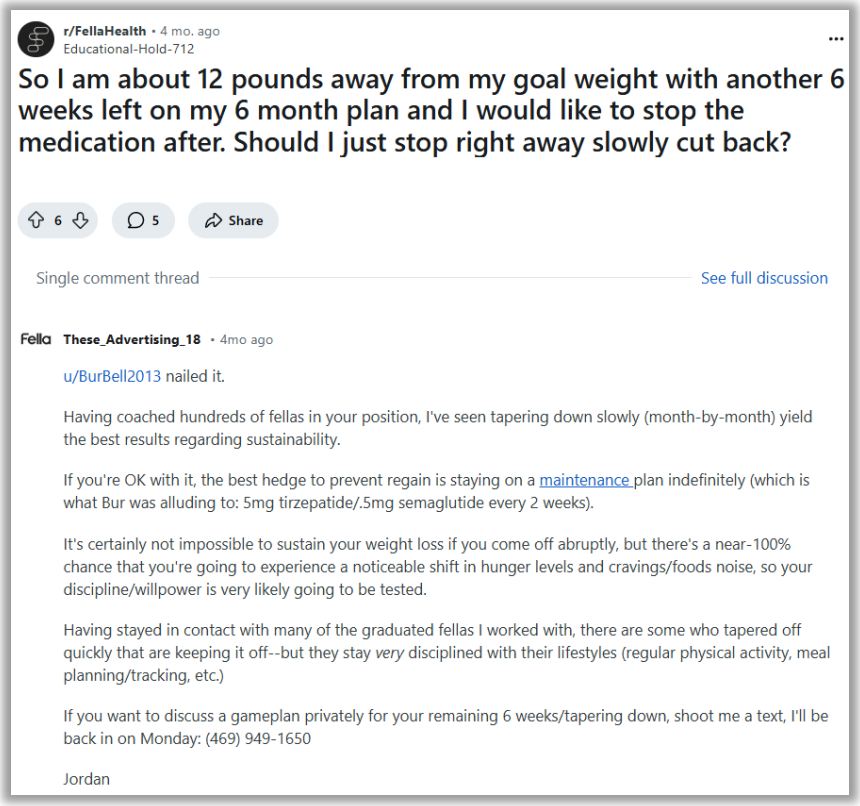


60. Cartwright is not the only non-medical Fella employee to offer medical advice to Fella customers. When another customer announced their weight loss results, the unlicensed Whitaker provided medical advice about proper dosing and instructed that "if you have a [sic] average weight that you want to lose per week/month based on your tracking, then I would suggest increasing your dose when you go below that."[46]

61. Non-physician Pellikan also frequently provides medical guidance. In one instance, a Fella customer asks whether they should modify their treatment schedule. Despite his lack of medical licensure, Pellikan responds with instruction on how to adjust the patient's doses, stating, "Having coached hundreds

[46] Reddit, *4 months, down 13lbs - thoughts?*, (Dec. 12, 2024), https://www.reddit.com/r/FellaHealth/comments/1hcpvlz/4_months_down_13lbs_thoughts/ (last accessed on Apr. 11, 2025).

of fellas in your position, I've seen tapering down slowly (month-by-month) yield the best results regarding sustainability. If you're OK with it, the best hedge to prevent regain is staying on a maintenance plan indefinitely (which is what [another user] was alluding to: 5mg tirzepatide/.5mg semaglutide every 2 weeks)."[47] Later, Pellikan offers his personal phone number to the customer to "discuss a gameplan privately."[48]



62. And in another exchange, Pellikan assesses the effectiveness of a patient's current treatment; recommends the patient start another prescription drug, metformin; and offers his personal number to "assist" the patient "getting started on the metformin also."[49]

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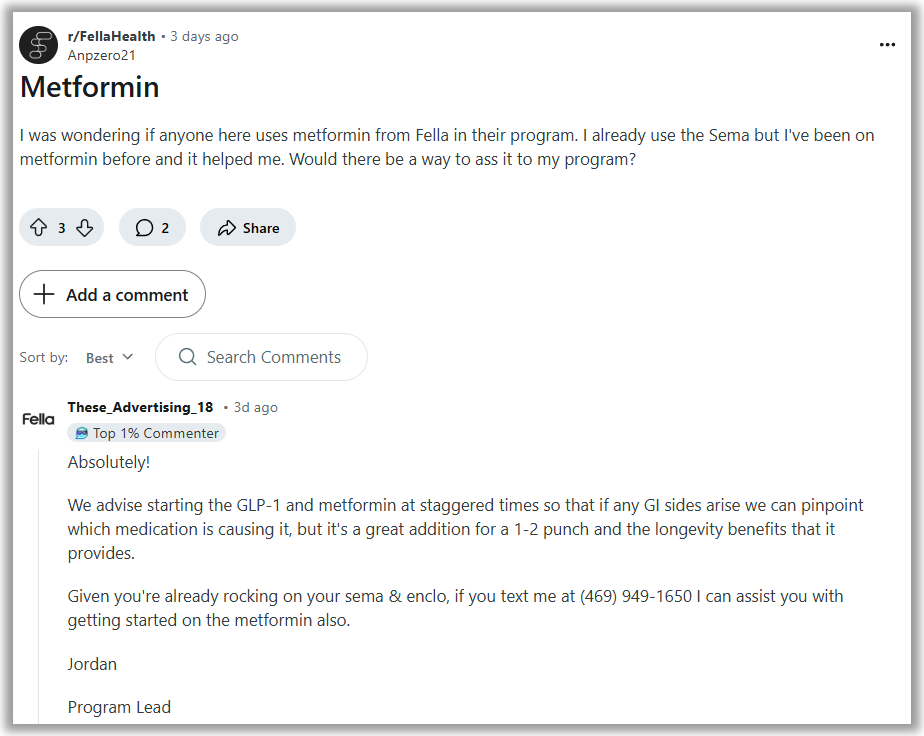
[47] Reddit, *So I am about 12 pounds away from my goal weight with another 6 weeks left on my 6 month plan and I would like to stop the medication after. Should I just stop right away slowly cut back?*, (Dec. 6, 2024) https://www.reddit.com/r/FellaHealth/comments/1h8eprw/so_i_am_about_12_pounds_away_from_my_goal_weight/ (last accessed on Apr. 11, 2025).

[48] *Id*.

[49] Reddit, *Metformin*, (Mar. 31, 2025), https://www.reddit.com/r/FellaHealth/comments/1jo937p/metformin/ (last accessed on Apr. 11, 2025).



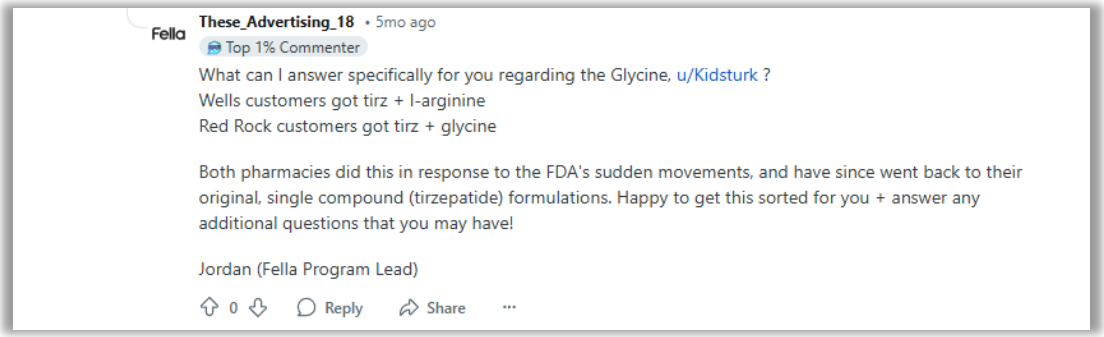
63. This sort of direct engagement by individuals with no medical licensure violates California's bar against the unlicensed practice of medicine by individuals and corporations. Fella's practice is particularly egregious here, where the most common recommendation given by its non-physician employees to their customers financially benefits the corporation: increasing the dosage and accelerating the titration schedule of Fella's knockoff compounded products that are not working for those patients and prescribing more medicine through Fella.

2. Fella Changed Patient Prescriptions En Masse

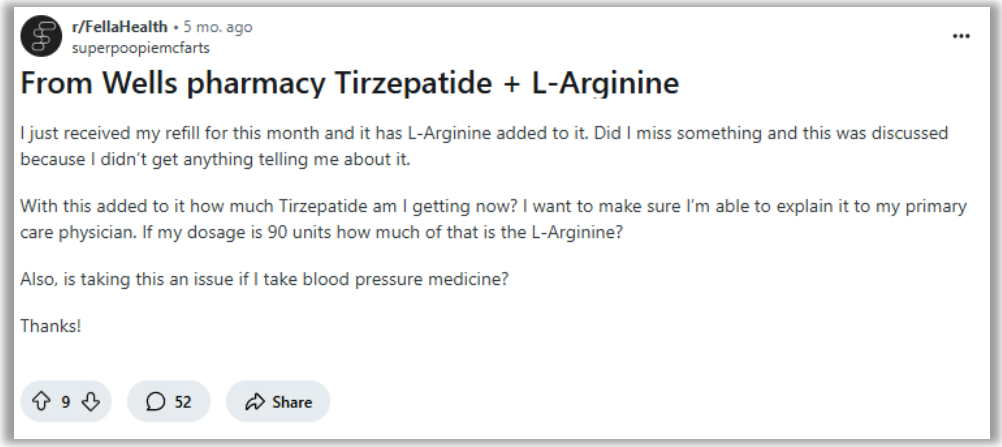
64. In yet more unlawful corporate practice of medicine, Fella has unilaterally required its patients to change their prescriptions for compounded tirzepatide to ones for doses manipulated with additives—changes made for Fella's own financial reasons, not to advance patient care. Changing patients' prescriptions en masse based on the business needs of the corporation, instead of individualized patient needs, flatly contradicts the requirement that prescribing decisions must be based on a "medical indication." Cal. Bus. & Prof. Code § 2242.

65. As one example, in November 2024, Fella switched patients' prescriptions from compounded tirzepatide ***without*** any additives to manipulated formulations ***with*** additives—either l-

arginine or glycine.[50] In other words, before November 2024, these Fella patients received tirzepatide compounded without any additives, and after this date, they began receiving a tirzepatide/glycine or tirzepatide/l-arginine combination. These combinations are not FDA approved and have never been evaluated in any clinical study for safety or effectiveness. Fella then quickly thereafter switched the patients back to tirzepatide without additives.



66. Fella patients had the formulation of their prescription changed en masse based on Fella's financial interests, and not based on any individual patient's clinical need. Many patients learned of the "surprise additive" or "different additive" not through their doctor but rather when their prescription arrived from Fella Health. As one patient explained: "I just received my refill for this month and it has L-Arginine added to it. Did I miss something and this was discussed because I didn't get anything telling me about it."[51]

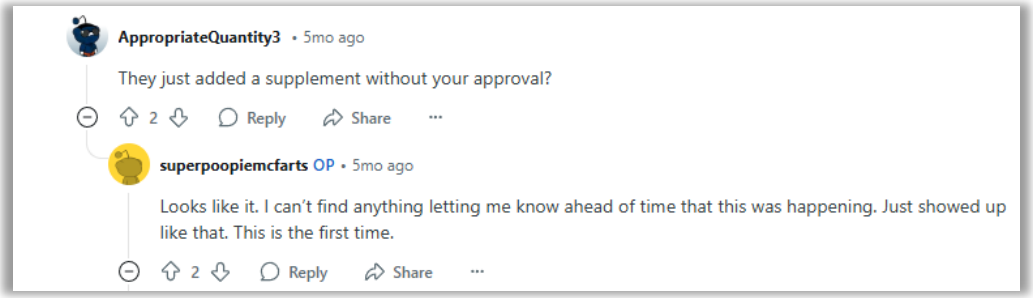


[50] Reddit, *From Wells pharmacy Tirzepatide + L-Arginine*, https://www.reddit.com/r/FellaHealth/comments/1gan4mj/from_wells_pharmacy_tirzepatide_larginine/ (last accessed Apr. 11, 2025).

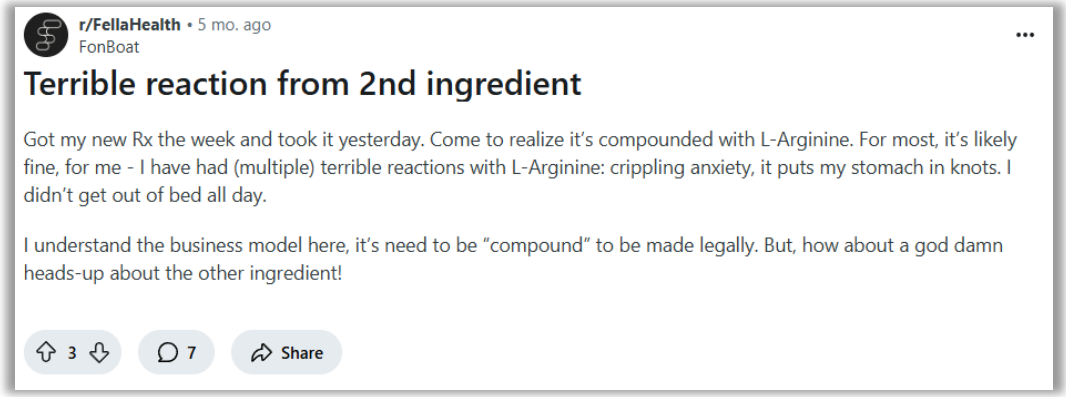
[51] *Id.*

67. Many patients expressed confusion, concern, and frustration with having their prescription "diluted" or changed to include "different additive" and "surprise additive" without notification or consultation.

68. One patient confirmed that Fella "just added a supplement without [my] approval" and noted "I can't find anything letting me know ahead of time that this was happening. Just showed up like that. This is the first time."[52]



69. Worse yet, some patients only learned about the formulation change after they experienced new side effects, with one patient explaining, "I have had (multiple) terrible reactions with L-Arginine: crippling anxiety, it puts my stomach in knots. I didn't get out of bed all day. . . . [H]ow about a god damn heads-up about the other ingredient!"[53]



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52 *Id.*

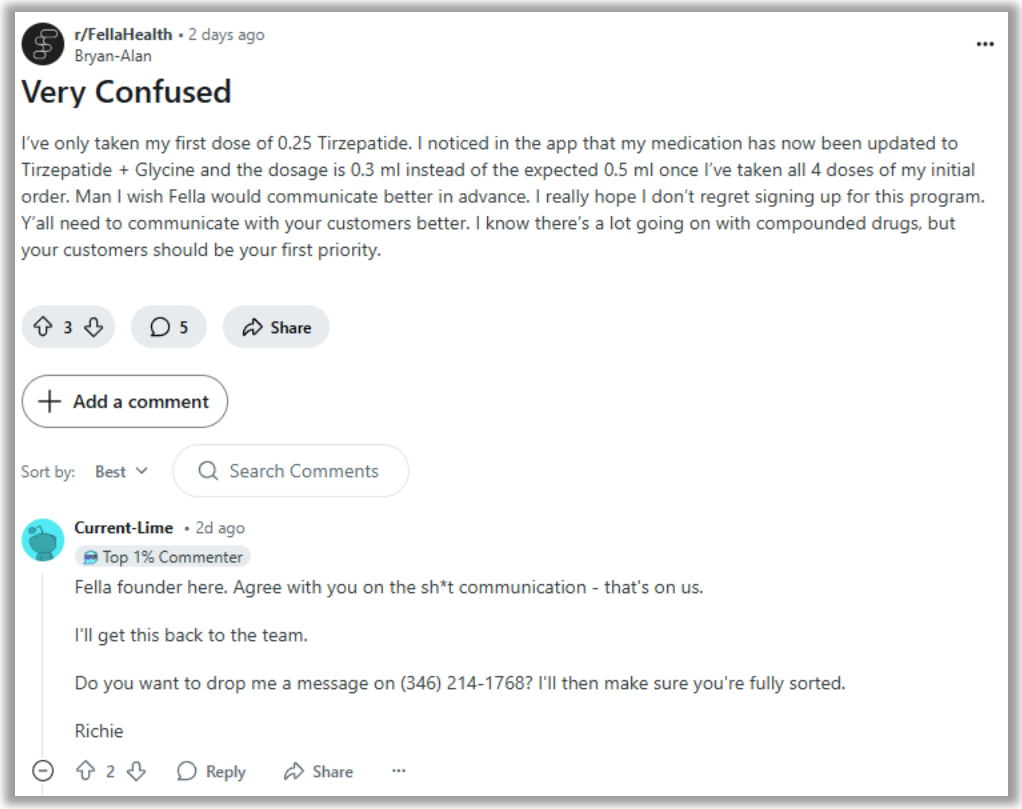
53 Reddit, *Terrible reaction from 2nd ingredient,* https://www.reddit.com/r/FellaHealth/comments/1gdc886/terrible_reaction_from_2nd_ingredient/ (last accessed Apr. 11, 2025).

70. Fella made a similar change for a second time in April 2025, when it once again changed patients' prescriptions en masse—this time unilaterally switching patients from compounded tirzepatide alone to a modified formula containing glycine.[54]

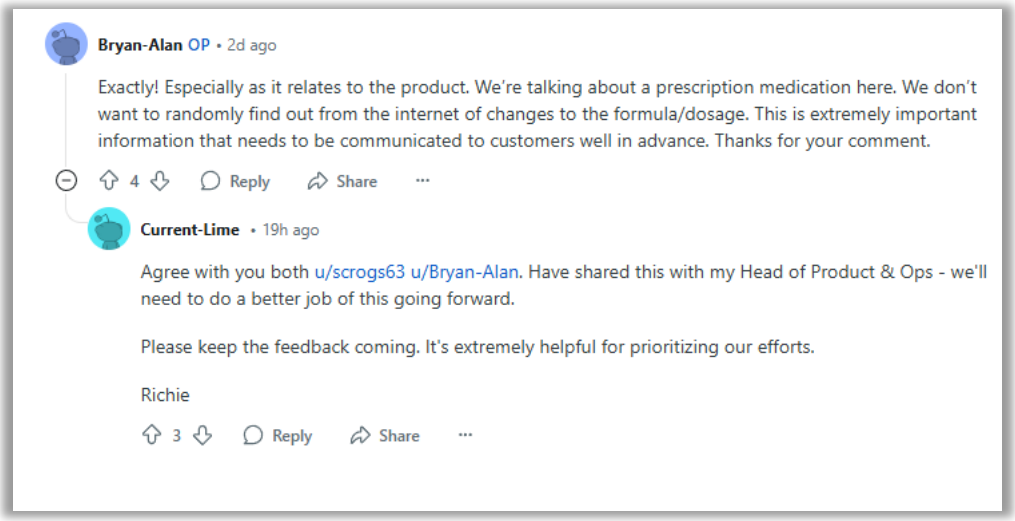
71. Once again, many patients learned of the change not through their doctor or even from the non-physicians at Fella—only when they received their prescription. A customer described their surprise at seeing the uncommunicated and unauthorized change: "I've only taken my first dose of 0.25 Tirzepatide. I noticed in the app that my medication has now been updated to Tirzepatide + Glycine and the dosage is 0.3 ml instead of the expected 0.5 ml once I've taken all 4 doses of my initial order. Man I wish Fella would communicate better in advance."[55]

[54] Reddit, *Product Change?!?*, https://www.reddit.com/r/FellaHealth/comments/1jpq6tg/product_change/ (last accessed Apr. 11, 2025).

[55] Reddit, *Very Confused*, https://www.reddit.com/r/FellaHealth/comments/1jpaigm/very_confused/ (last accessed Apr. 11, 2025).



72. Another patient expressed similar concern, again showing the lack of physician-patient interaction: "We're talking about a prescription medication here. We don't want to randomly find out from the internet of changes to the formula/dosage. This is extremely important information that needs to be communicated to customers well in advance."[56]



[56] *Id.*

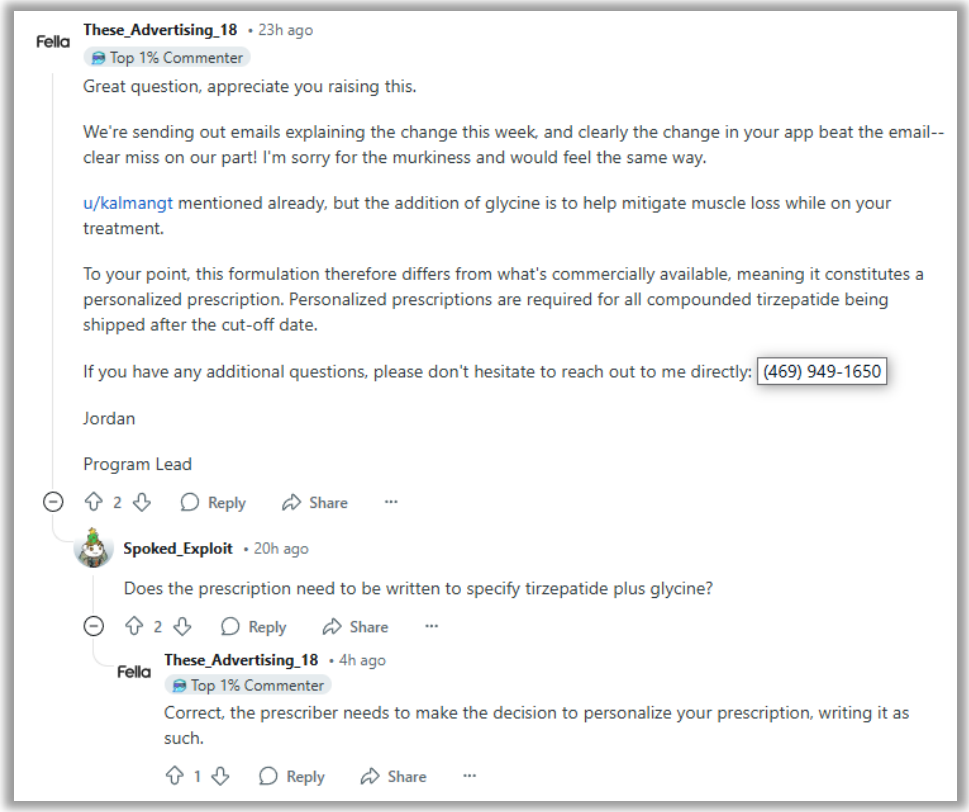
73. There was no medical reason to unilaterally change prescriptions for Fella's patients en masse to change from unmodified compounded tirzepatide to tirzepatide mixed with l-arginine or glycine, back to unmodified compounded tirzepatide, then back to tirzepatide mixed with glycine—all in a matter of months.

74. These changes were instead driven by Fella's financial interests and its corporate influence on prescribing decisions. Indeed, when patients questioned "why Fella is making these type[s] of changes without communication[,]" Pellikan explained his mistaken belief that this change would allow the company to continue selling tirzepatide—*i.e.*, making money. He stated (again mistakenly) that by adding glycine, the "formulation therefore differs from what's commercially available, meaning it constitutes a personalized prescription. Personalized prescriptions are required for all compounded tirzepatide being shipped after the cut-off date."[57] When Pellikan refers to a "cut-off date" he is alluding to an FDA declaratory order that compounding pharmacies cease mass-compounding knockoff tirzepatide by, at the latest, March 19, 2025.[58] Fella apparently mistakenly believed that adding glycine to Fella's knockoff tirzepatide would allow Fellow to continue to sell compounded knockoff products. Still, Pellikan continued that the "prescriber needs to make the decision to personalize your prescription, writing it as such."[59] But Pellikan's message makes clear that the change was made based on Fella's mistaken understanding of the "cut-off date," and not based on an individual prescriber's decision for individual patients.

[57] Reddit, *Product Change?!?*, https://www.reddit.com/r/FellaHealth/comments/1jpq6tg/product_change/ (last accessed Apr. 11, 2025).

[58] FDA, *FDA clarifies policies for compounders as national GLP-1 supply begins to stabilize* (Mar. 10, 2025), https://www.fda.gov/drugs/drug-safety-and-availability/fda-clarifies-policies-compounders-national-glp-1-supply-begins-stabilize.

[59] Reddit, *Product Change?!?*, https://www.reddit.com/r/FellaHealth/comments/1jpq6tg/product_change/ (last accessed Apr. 11, 2025).



75. Fella repeatedly claims that it "write[s] personalized prescriptions for [its] existing compounded injectable tirzepatide patients,"[60] or that it is "offering personalized tirzepatide prescriptions."[61] However, Fella is not providing personalized prescriptions at all. Fella offers an untested, unapproved, one-size-fits-all drug to patients, ***not*** a "personalized product." And it does so by changing patient formulations en masse and without notice to customers or a prior determination of clinical need from the customers' physician.[62]

76. In short, Fella has repeatedly altered patient prescriptions by corporate fiat without a medical indication for the alteration, without providers driving those changes for individual patients, and

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[60] Reddit, *What's this with the FDA and tirzepatide?*, https://www.reddit.com/r/FellaHealth/comments/1jn7nn9/whats_this_with_the_fda_and_tirzepatide/mkitfb7/ (last accessed Apr. 11, 2025); Reddit, *For those on Tirz and pre-bought 3/6 months- what's your plan?*, https://www.reddit.com/r/FellaHealth/comments/1jmoy5e/for_those_on_tirz_and_prebought_36_months_whats/mkir6zv/ (last accessed Apr. 11, 2025).

[61] Reddit, *For those on Tirz and pre-bought 3/6 months- what's your plan?*, https://www.reddit.com/r/FellaHealth/comments/1jmoy5e/for_those_on_tirz_and_prebought_36_months_whats/ (last accessed Apr. 11, 2025).

[62] Reddit, *Product Change?!?*, https://www.reddit.com/r/FellaHealth/comments/1jpq6tg/product_change/ (last accessed Apr. 11, 2025).

without even prior notice to the patients. These alterations, made by a corporate entity for business purposes and without medical indication, violate California's corporate practice of medicine doctrine and other state physician-practice laws.

C. Fella Changes Prescriptions for Its Patients Without Good Faith Examination or Medical Indication

77. Fella's arbitrary, business-driven prescription changes violate not only California's prohibition on the unlicensed, corporate practice of medicine but also California Business & Professions Code § 2242, which makes clear that "[p]rescribing, dispensing, or furnishing dangerous drugs as defined in Section 4022 [*i.e.*, a prescription drug] without an appropriate prior examination and a medical indication, constitutes unprofessional conduct." Bus. & Prof. Code § 2242. The healthcare professional is required to comply with "the appropriate standard of care." The standard of care requires a "prior examination and a medical indication" that the prescription is warranted.

78. This standard cannot be met where, as here, company employees without medical licenses direct the medical care of patients and where the company changes prescriptions en masse for business purposes, as described above.

V. FELLA'S UNFAIR COMPETTION AND UNFAIR, DECEPTIVE, FALSE, MISLEADING, AND UNLAWFUL MARKETING AND SALE OF TIRZEPATIDE

A. Fella Unlawfully Sells Untested Oral Tirzepatide

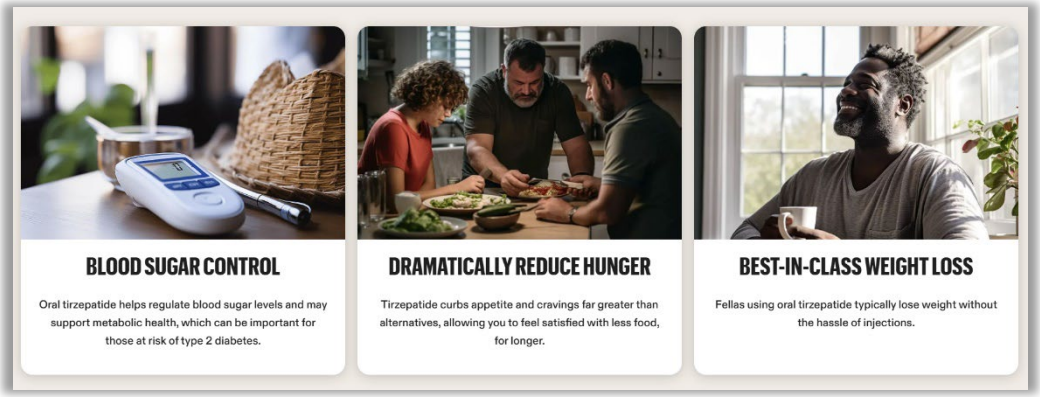
79. Fella's unlawful conduct runs deeper than just the unlawful practice of medicine by unlicensed individuals at a non-medical corporation. To obtain its customers in the first place, Fella engages in unfair competition and false, unfair, misleading, and deceptive promotion and sales of its oral and injectable tirzepatide.

1. Fella's Sale of Unproven Oral Tirzepatide That It Acknowledges Does Not Work

80. First, Fella's unlawful sale of an oral tirzepatide product that it knows does not work is deceptive, misleading, and constitutes unfair competition.

81. Fella tells consumers oral tirzepatide is "a GLP-1 medication that helps regulate appetite and support weight management. Taken as daily pills, it offers a convenient option for those looking to

reach their weight loss goals."[63] On its oral tirzepatide product page, Fella Health states that oral tirzepatide helps with blood sugar control," "dramatically reduce[s] hunger," and provides "best-in-class weight loss." Fella further states that oral tirzepatide "curbs appetite and cravings far greater than alternatives," and patients "using oral tirzepatide typically lose weight without the hassle of injections."[64]



82. Fella also tells consumers that "Fellas using oral tirzepatide typically lose weight without the hassle of injections," suggesting that its product is at least comparable to an injectable tirzepatide medicine in terms of outcomes, yet even more convenient and "less hassle" than Lilly's FDA-approved injectable medicines.

83. Fella even tells patients that its untested oral drug is ***better*** than Lilly's approved medicines. Fella claims its oral tirzepatide "delivers results that outperform traditional weight loss methods."[65] In other words, Fella is not only claiming to provide a safe and effective alternative treatment, but also one that offers ***superior*** outcomes to MOUNJARO® and ZEPBOUND®. Of course, no studies exist to verify Fella's claims.

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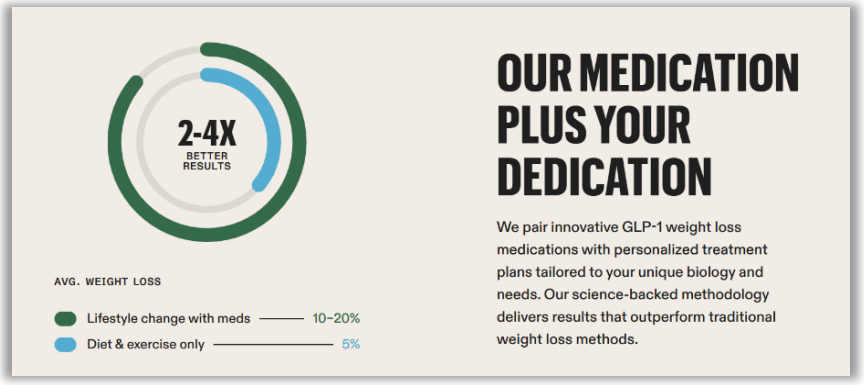
[63] Fella Oral Tirzepatide Product Page, https://www.fellahealth.com/oral-tirzepatide-glp-1-medication (last accessed Apr. 11, 2025).

[64] *Id.*

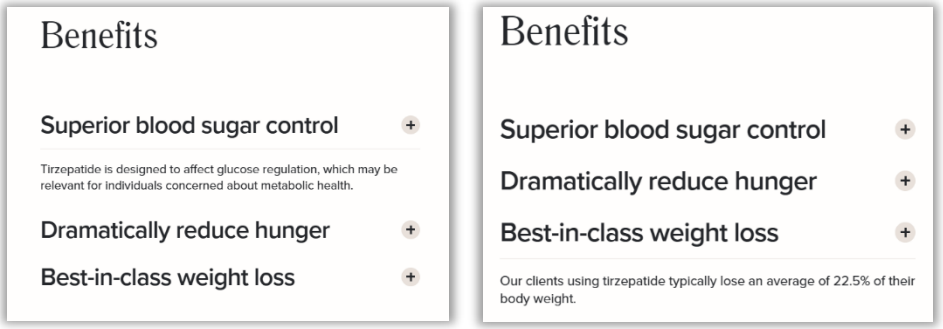
[65] *Id.*



84. Delilah makes similar claims. On its oral tirzepatide product page, Delilah states that oral tirzepatide "is the most innovative GLP-1 medication proven to dramatically curb appetite, hunger, and cravings to help busy men achieve substantial weight loss."[66] Delilah also claims that this product offers "15% avg. weight loss."

85. Delilah further states that oral tirzepatide offers "[s]uperior blood sugar control" and that patients "typically lose an average of 22.5% of their body weight."

[66] Delilah Oral Tirzepatide Product Page, https://www.joindelilah.com/oral-tirzepatide-glp-1-medication (last accessed on Apr. 11, 2025).



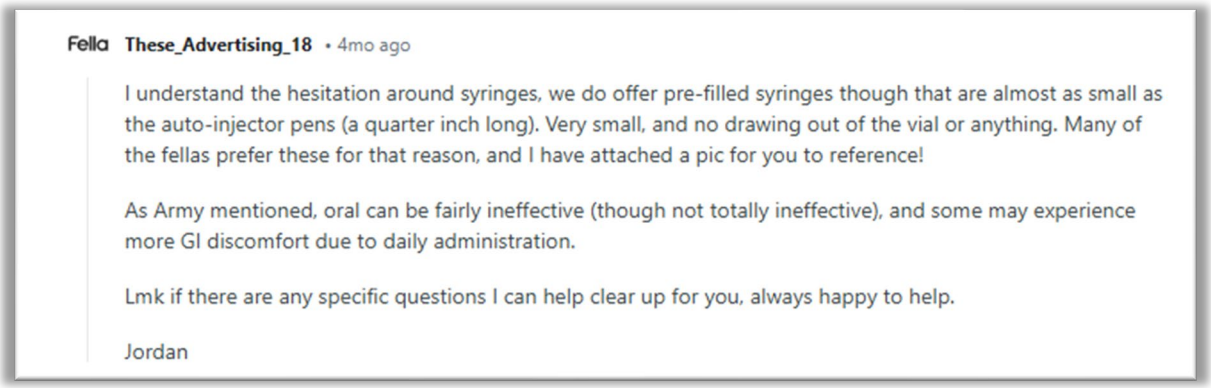
86. Further down on the same product page, Delilah states that oral tirzepatide has "high" effectiveness, just like injectable tirzepatide.

87. These statements communicate to consumers that Fella's oral tirzepatide product is safe and effective, and proven to provide the advertised health benefits.

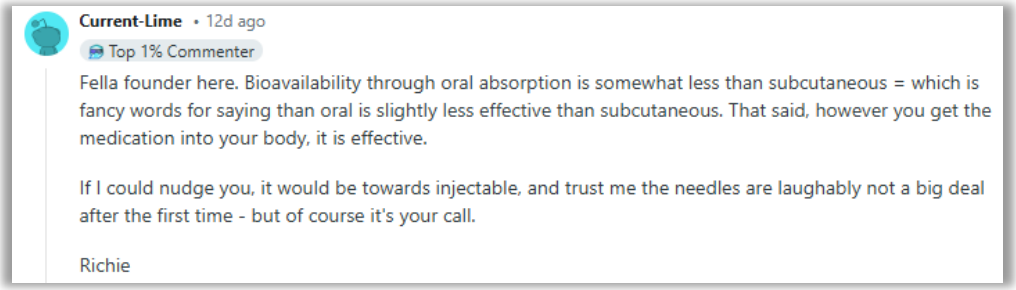
88. Yet that is simply not true. Lilly's ZEPBOUND® and MOUNJARO® medicines are the only tirzepatide medicines that have been clinically tested and proven to be safe and effective. They are only available—and have only been FDA-approved—in injectable form and in specific doses. There are material differences in bioavailability between an oral product and a subcutaneous injection. The results of Lilly's own clinical trials on its injectable products say nothing about how Fella's untested oral product may work. Fella has no basis to claim that its compounded tablets are safe and effective. Indeed, Fella has no evidence that ***any*** of the purported tirzepatide in its tablets will reach the bloodstream.

89. Despite these representations on its website, Fella leaders have acknowledged that Fella's oral tirzepatide product does not work as advertised.

90. On Reddit, Pellikan acknowledged that "oral can be fairly ineffective" and that "some may experience GI discomfort due to daily administration."[67]



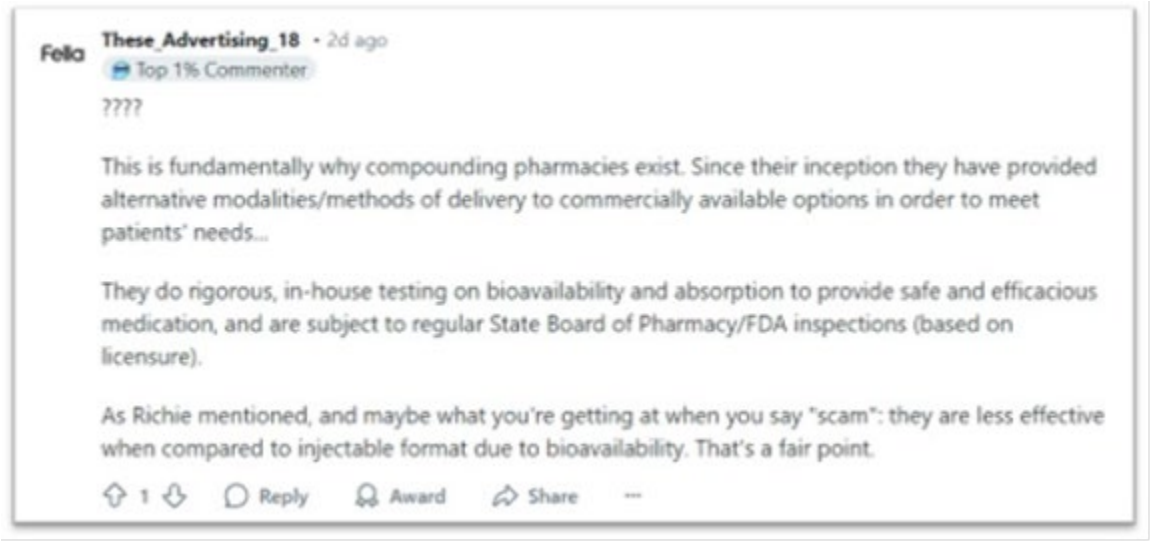
91. When another customer asked about personal experiences with Fella's untested oral drugs, Cartwright demonstrated that Fella already knew that oral medication was, at least, not as effective, explaining that "[b]ioavailablity through oral absorption is somewhat less than subcutaneous = which is fancy words for saying that oral is slightly less effective than subcutaneous" and stating, "[i]f I could nudge you, it would be towards injectable."[68] However, Cartwright has no basis to claim that "oral absorption" is only "***somewhat*** less than subcutaneous" or that oral tirzepatide is only "***slightly*** less effective than subcutaneous" because there is no clinical evidence that oral tirzepatide has ***any*** absorption into the bloodstream or that it has ***any*** effectiveness.



[67] Reddit, *What are these? This screenshot is from a recent ad on Facebook*, (Dec. 19, 2024) https://www.reddit.com/r/FellaHealth/comments/1hi51db/comment/m2wj634/ (last accessed on Apr. 11, 2025).

[68] Reddit, *Is anyone taking Oral GLP-1? What's your experience.*,(Mar. 26, 2025) https://www.reddit.com/r/FellaHealth/comments/1jk4kfu/is_anyone_taking_oral_glp1_whats_your_experience/ (last accessed on Apr. 11, 2025).

92. Similarly, rather than contest the lack of effectiveness of oral tirzepatide, when confronted by a customer insisting oral tirzepatide is a "scam," Pellikan responded, "That's a fair point," because oral tirzepatide is "less effective when compared to injectable format due to bioavailability."[69] Pellikan also claimed that the compounding pharmacies that provide Fella with oral tirzepatide "do rigorous, in-house testing on bioavailability and absorption to provide safe and efficacious medication."[70] Pellikan did not identify any source for this claim that oral tirzepatide has been subjected to rigorous testing for bioavailability, safety, or effectiveness.



93. And despite touting oral tirzepatide as offering the benefit of "[n]o hassle of injections," Fella also recognizes that injections are ***not*** actually a hassle. Fella leadership regularly tells patients on social media that "needles are laughably not a big deal"[71] and "feel like almost nothing at all,"[72] that using needles is "super easy,"[73] and that injectables are "so easy for people to administer."[74] In fact, Whitaker

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69 https://www.reddit.com/r/FellaHealth/comments/1jxeepj/getting_my_tirzepatide_oral_next_week/?rdt=60672 (last accessed on Apr. 11, 2025)

70 *Id.*

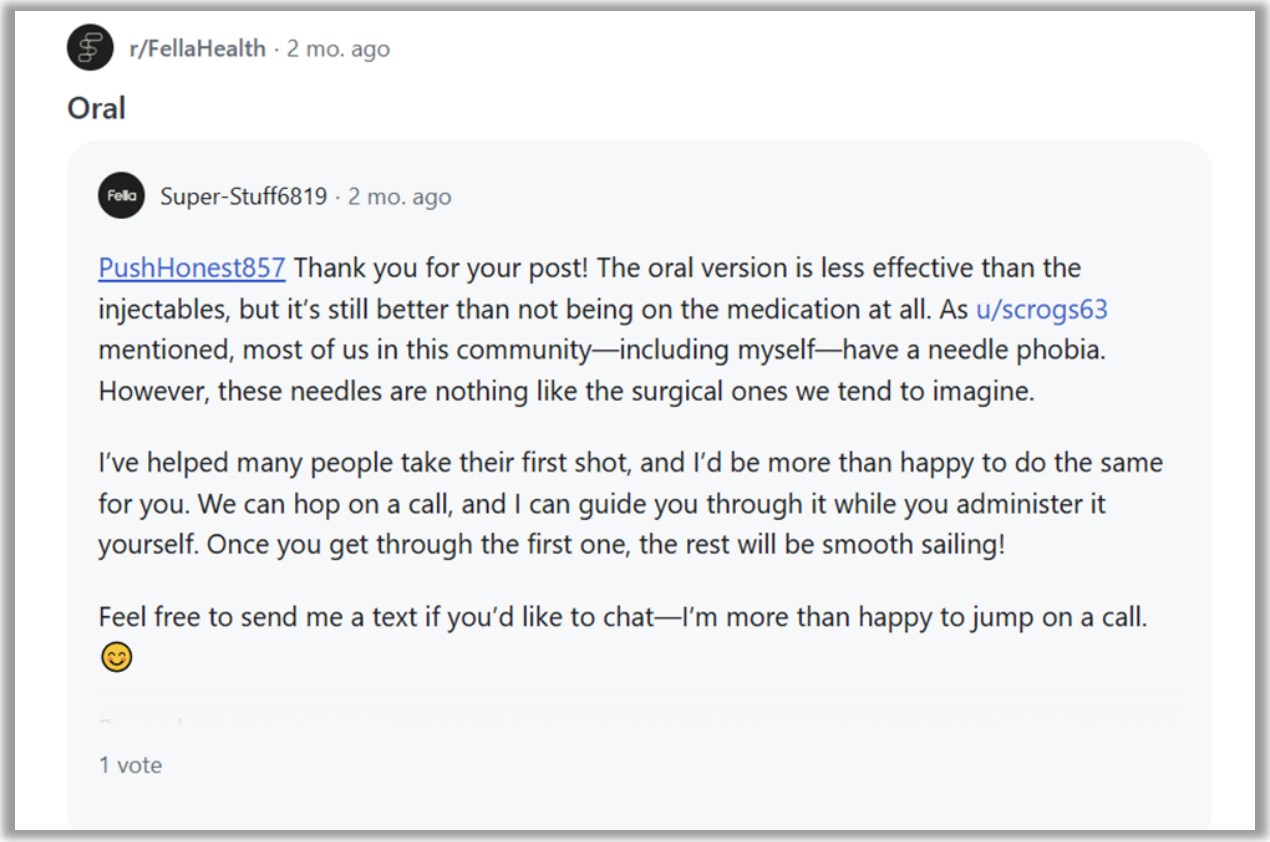
71 *Id.*

72 Reddit, *Was it easy to do a first shot? I have never done it before.*, (Apr. 2, 2025) https://www.reddit.com/r/FellaHealth/comments/1jpahbi/comment/ml0jp2u/ (last accessed on Apr. 11, 2025).

73 Reddit, *First dose* ✅, (Feb. 19, 2025) https://www.reddit.com/r/FellaHealth/comments/1itfyxy/first_dose/mdormlg/ (last accessed on Apr. 11, 2025).

74 Reddit, *First Dose Easy!,* (Feb. 14, 2025) https://www.reddit.com/r/FellaHealth/comments/1ipd3n7/comment/mcr9661/ (last accessed on Apr. 11, 2025).

told patients that "[t]he oral version is less effective than the injectables" and that using needles is "smooth sailing," all in the same Reddit comment.[75]



94. In sum, Fella engages in unfair competition when it sells untested oral tirzepatide that it knows does not work, and when it tells patients that injections are a "hassle" when it knows this isn't true—all to steer patients away from Lilly's tested, proven medicines.

2. Fella Falsely Claims That the Safety and Effectiveness of Its Oral Tirzepatide Is Scientifically Supported

95. Second, to push its unapproved knockoff oral tirzepatide, Fella falsely, deceptively, misleadingly, and unfairly tells customers that oral tirzepatide is supported by science and clinical studies.

96. Oral tirzepatide has never been studied in clinical trials, and Fella has no "science" supporting its oral product. Fella's unlawful conduct risks luring patients away from FDA-approved injectable products to Fella's ineffective and unapproved knockoffs.

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[75] Reddit, *Oral,* (Feb. 13, 2025) https://www.reddit.com/r/FellaHealth/comments/1iovbpm/comment/mcn377i/ (last accessed on Apr. 11, 2025).

97. Fella's website explicitly states that its oral tirzepatide is "Science-Backed" and that Fella uses a "science-backed methodology."[76] Similarly, Pellikan told consumers that patients experience approximately 15% weight loss in one year when using oral tirzepatide.[77] But there are no clinical studies demonstrating that patients using oral tirzepatide experience an average of 15% weight loss. In fact, there is no "science" at all evaluating the patient outcomes of oral tirzepatide, and no clinical studies assessing the effectiveness of oral tirzepatide.

98. Fella misleads its customers by referencing ***Lilly's*** clinical trials as evidence in support of Fella's knockoff oral versions. For example, Delilah's website states that its "advanced oral Tirzepatide treatment" was "developed through cutting edge research."[78] Delilah also states that patients can lose 15% of their starting weight, relying on the same clinical trial data Fella Health uses to support claims that oral tirzepatide is effective, and that patients using oral tirzepatide experience "22.5% [average] weight loss."[79] This figure is derived explicitly from Lilly's SURMOUNT-1 trial. But Lilly's clinical trials studied ***Lilly's injectable*** tirzepatide.[80] Lilly's studies did not assess the effectiveness of any oral tirzepatide—or any compounded drug at all.

99. Fella's use of Lilly's clinical trials to support its effectiveness claims is false, unfair, deceptive, and misleading. As noted above, there are material differences in bioavailability between an oral product and a subcutaneous injection. Fella's founder acknowledges this.[81] Accordingly, the results of Lilly's clinical trials on its injectable products do not support the purported effectiveness of Fella's untested oral drug. Fella has no basis to claim that its oral tirzepatide will have any impact on glucose

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[76] Fella Health Oral Tirzepatide Product Page, https://www.fellahealth.com/oral-tirzepatide-glp-1-medication (last accessed on Apr. 11, 2025).

[77] Reddit, *Oral Tirzepatide*, (Mar. 7, 2025), https://www.reddit.com/r/FellaHealth/comments/1j69ltp/oral_trizepatide/ (last accessed on Apr. 11, 2025).

[78] Delilah Oral Tirzepatide Product Page, https://www.joindelilah.com/oral-tirzepatide-glp-1-medication (last accessed on Mar. 17, 2025).

[79] Delilah Oral Tirzepatide 6 month plan, https://www.joindelilah.com/step-1?plan=sixMonthOralTirzepatide (last accessed on Mar. 9, 2025).

[80] Ania M. Jastreboff, et al. *Tirzepatide Once Weekly for the Treatment of Obesity* (June 4, 2022), available at https://www.nejm.org/doi/full/10.1056/NEJMoa2206038#:~:text=The%20mean%20percentage%20change%20in,placebo%20(P%3C0.001%20for%20all.

[81] Reddit, *Is anyone taking Oral GLP-1? What's your experience.*,(Mar. 26, 2025) https://www.reddit.com/r/FellaHealth/comments/1jk4kfu/is_anyone_taking_oral_glp1_whats_your_experience/ (last accessed on Apr. 11, 2025)

regulation, metabolic health, or that it can lead to the loss of 15% of one's body weight—or even any weight loss—since Fella has no evidence that ***any*** of the purported tirzepatide in its tablets will reach the bloodstream.

100. Moreover, Fella's references to "Science-Backed" products developed through "cutting edge research" are clear establishment claims that must be supported by the sort of testing described in the advertisement. But Fella does not possess any data of the sort, and Lilly's clinical trials of injectable, FDA-approved medicines do not substantiate claims about Fella's knockoff tirzepatide drugs.

B. Fella Deceptively Promotes Its Injectable Tirzepatide as Safe and Effective

101. Fella also offers a compounded injectable tirzepatide product (previously without additives, now mixed with various additives), and likewise unfairly, misleadingly, deceptively, and falsely markets and sells that product. Fella's unlawful conduct related to its compounded injectable tirzepatide has harmed and continues to harm Fella patients because, Fella continues to prescribe these products for its existing patients.[82]

102. For instance, Fella told its customers they could "feel confident using FDA-approved GLP-1 medications, which have been scientifically proven safe and effective for weight loss in men."[83] But Fella's injectable (like its oral) tirzepatide is untested and scientifically unproven, and FDA has never approved it. Fella's claims of offering "proven treatments" that make achieving weight loss goals "simple and safe" ring hollow in light of Fella's complete lack of empirical proof for these claims, to their customers' detriment. Moreover, by claiming to offer "proven treatments," Fella necessarily trades on Lilly's brand and customer goodwill by promising results that consumers will not obtain from Lilly's clinically tested and FDA-approved medicines. If Fella's untested products prove ineffective or if consumers are harmed by taking them, they may draw unwarranted conclusions about the safety and effectiveness of Lilly's FDA-approved tirzepatide medicines.

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[82] Reddit, *What's this with the FDA and tirzepatide?* (Mar. 30, 2025) https://www.reddit.com/r/FellaHealth/comments/1jn7nn9/comment/mkitfb7/ (last accessed on Apr. 11, 2025).; Reddit, *Product Change?!?* (Apr. 2, 2025) https://www.reddit.com/r/FellaHealth/comments/1jpq6tg/comment/ml41fi5/?context=3 (last accessed on Apr. 11, 2025).

[83] Fella Health Previous Tirzepatide Product Page, https://web.archive.org/web/20241212125925/https://www.fellahealth.com/tirzepatide-glp-1.

103. Fella still makes these statements about its injectable tirzepatide product. For example, Delilah's website still lists compounded injectable tirzepatide as having "high" effectiveness.[84]

104. But as with Fella's oral tirzepatide, Fella's compounded injectable tirzepatide product has never been shown to result in *any* "weight loss" and has never been tested for effectiveness or approved by any regulator.

105. Fella's earlier sales of injectable tirzepatide were even more egregious. Fella presented its untested and unproven injectable tirzepatide as "the most effective GLP-1 medication" and "[h]ighly effective for blood glucose control and weight loss."[85] Fella further promoted its compounded injectable product as "the most innovative GLP-1 medication proven to dramatically curb appetite, hunger, and cravings to help busy men achieve substantial weight loss" despite a total lack of proof backing these claims.[86] As with Fella's oral tirzepatide product, Fella promoted its injectable tirzepatide with claims of "best-in-class weight loss" and "superior blood sugar control," promising it "curbs appetite and cravings far greater than alternatives" and that patients "typically lose an average of 22.5% of their body weight."[87] This figure is derived from Lilly's SURMOUNT-1 trial, which evaluated Lilly's injectable tirzepatide medicines, ***not*** Fella compounded drugs.[88]

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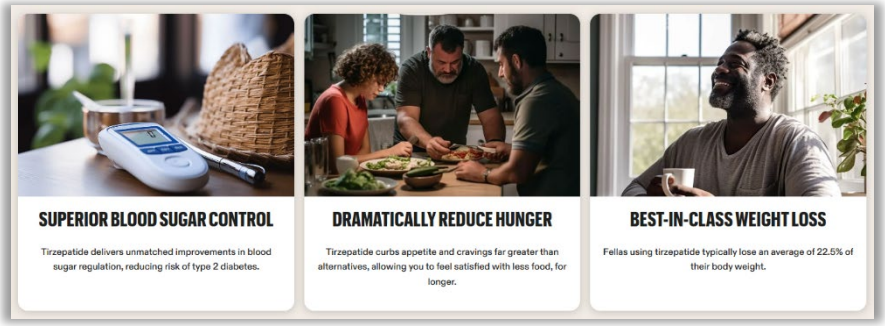
[84] Delilah Oral Tirzepatide Product Page, https://www.joindelilah.com/oral-tirzepatide-glp-1-medication (last accessed on Mar. 17, 2025).

[85] Fella Health Previous Home Page, https://web.archive.org/web/20250225211621/https://www.fellahealth.com/.

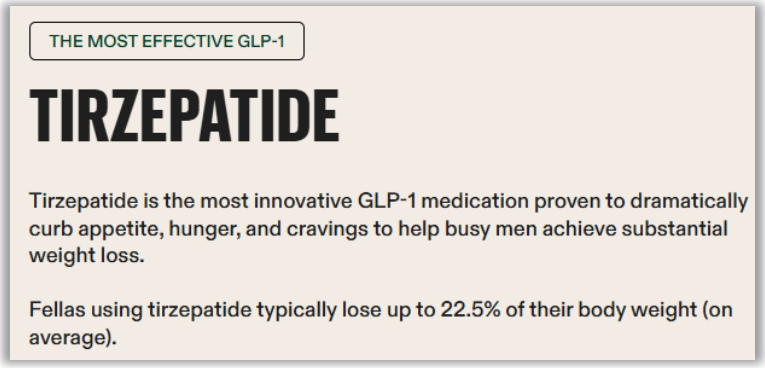
[86] Fella Health Previous Tirzepatide Product Page, https://web.archive.org/web/20241212125925/https://www.fellahealth.com/tirzepatide-glp-1.

[87] *Id.*

[88] Lilly's tirzepatide delivered up to 22.5% weight loss in adults with obesity or overweight in SURMOUNT-1 (Apr. 28, 2022), https://investor.lilly.com/news-releases/news-release-details/lillys-tirzepatide-delivered-225-weight-loss-adults-obesity-or.



106. Fella not only claimed that its untested and unapproved injectable drug is safe and effective, but also that it was ***superior*** to Lilly's medicines. For example, Fella Health stated that its injectable tirzepatide "delivers proven results that outperform traditional weight loss methods."[89] Fella Health also advertised its tirzepatide as "THE MOST EFFECTIVE GLP-1."[90] Fella does not offer the most effective GLP-1 and has no evidence to support that claim. This too is unfair, false, misleading, and deceptive.



107. In sum, Fella trades on Lilly's reputation as a trusted manufacturer of safe and effective tirzepatide medicines by promoting its injectable tirzepatide as an equivalent or superior alternative to medicines like MOUNJARO® and ZEPBOUND®, contending that it is at least as safe and effective as Lilly's medicines when it is not.

VI. FELLA'S UNLAWFUL CONDUCT HARMS CONSUMERS AND LILLY

108. Fella's unlawful corporate practice of medicine and its false, unfair, misleading and deceptive actions have harmed consumers and Lilly. This harm will continue if left unchecked.

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89 *Id.*

90 *Id.*

109. ***First***, Fella's unfair, deceptive, misleading, and false practices risk patient safety. Fella's unfair, deceptive, misleading, and wrongful business practices harm consumers by subjecting their medical decision-making process to Defendants' profit motivations and exposing them to the unnecessary risks associated with untested and unproven compounded tirzepatide.

110. ***Second***, Fella's unfair, deceptive, misleading, and false practices, including its false and misleading statements, cause irreparable harm to Lilly's brand and customer goodwill by promising results that consumers cannot obtain from Fella's product. Fella promotes its oral tirzepatide and compounded tirzepatide injections by trading on the credibility—earned through decades of safe and effective pharmaceutical manufacturing and years of clinical research and testing on tirzepatide specifically—of Lilly and its FDA-approved MOUNJARO® and ZEPBOUND®. When consumers fail to achieve desired results from Fella's oral tirzepatide or injectable tirzepatide, consumers may conclude that tirzepatide is ineffective in general—an outcome made more likely given Fella's reliance on Lilly's clinical studies. Worse still, if consumers are harmed using compounded tirzepatide products from Fella—where their dosage and formulation are subject to repeated changes based solely on Fella's business relationships and their dosage is arbitrarily changed without any clinical justification—consumers may even draw unwarranted conclusions about the safety and effectiveness of Lilly's FDA-approved tirzepatide medicines.

FIRST CAUSE OF ACTION

Unfair Competition
(Corporate Control of Practice of Medicine and Prescription Practices)
in Violation of the California Unfair Competition Law,
Cal. Bus. & Prof Code §§ 17200 *et seq.*

(Against All Defendants)

111. Lilly repeats and realleges each and every allegation above as if fully set forth herein.

112. The violations of law described in this Complaint have been, and are being, carried out and directed wholly or in part within the County of San Mateo and other locations within the State of California where Fella does business.

113. California Business and Professions Code § 17200 prohibits "unlawful, unfair or fraudulent business practices."

114. The deceptive and unfair business practices that Defendants employ to promote and sell their compounded tirzepatide drugs constitute violations of the California Unfair Competition Law.

115. Defendants have engaged within the last four years and continues to engage in unlawful and unfair business acts or practices in violation of Section 17200. Such acts and practices include, but are not limited to, the following:

- Unlawfully engaging in and aiding and abetting the unlawful Corporate Practice of Medicine within the State of California in violation of Business & Professions Code §§ 2400, 2502 *et al.*
- Unlawfully prescribing medications, including modifying the formulation, dosage, and titration schedule without an appropriate prior examination by a physician and without the identification of a medical indication for the modification. Cal. Bus. & Prof. Code § 2242.
- Unlawfully prescribing medications with additives and changing additives in the prescribed drug without an appropriate prior examination by a physician and without the identification of a medical indication for the modification. *Id.*
- Unlawfully prescribing untested oral and injectable drugs without conducting a good-faith exam and that, by Fella's own admission, do not work.

116. The business practices that Defendants have employed to promote and sell compounded tirzepatide products constitute "unlawful, unfair, or fraudulent" conduct under the California Unfair Competition Law, by permitting corporate interests to exert undue control over aspects of the physician / patient relationship, as described in Section IV, *supra*. The business practices further constitute "unlawful, unfair, or fraudulent" conduct under the California Unfair Competition Law by adding and modifying additives to drug products without examining the patient, and by prescribing oral and injectable drug products Defendants know do not work.

117. Defendants' unfair and unlawful conduct is interfering with Lilly's ability to conduct its business. As a direct and proximate result of Defendants' false and misleading campaign, Lilly is suffering immediate and continuing, competitive, irreparable injury for which there is no adequate remedy at law.

118. As a direct and proximate result of Defendants' deceptive and unlawful practices, Defendants have obtained an unfair and illegal business advantage, thereby benefitting and profiting from sales it made as a result of goodwill associated with Lilly's MOUNJARO® and ZEPBOUND® tirzepatide medicines. Lilly has suffered and will continue to suffer monetary damages that can be measured and quantified as well as discernible competitive injury by the loss of goodwill.

119. Lilly is entitled to all remedies available under the California Unfair Competition Law, including injunctive relief, restitution, and attorneys' fees.

SECOND CAUSE OF ACTION
Unfair Competition
in Violation of the California Unfair Competition Law,
Cal. Bus. & Prof Code §§ 17200 *et seq.*

(Against All Defendants)

120. Lilly repeats and realleges each and every allegation above as if fully set forth herein.

121. The California Unfair Competition Law applies when a plaintiff suffers injury from a competitor's unfair act or practice, including through an act that threatens or harms competition.

122. The deceptive and unfair business practices that Defendants employ to promote and sell their compounded tirzepatide drugs constitute violations of the California Unfair Competition Law.

123. Defendants employ deceptive unfair, and unlawful business practices by: (i) marketing and selling untested and unapproved oral and injectable compounded tirzepatide drugs as safe and effective and supported by clinical studies, (ii) marketing and selling those untested and unapproved drugs as FDA-approved, (iii) misleading consumers about the medical indication and necessity for changes in the formulation, dosage, and titration schedule of their drugs, (iv) falsely claiming that their tirzepatide drug is "personalized," (v) altering prescriptions for business purposes, and (vi) altering dosage for business purposes.

124. In doing so, Defendants lure consumers away from obtaining safe and effective treatment, such as Lilly's FDA-approved tirzepatide medicines. Defendants' unfair, deceptive, and unlawful conduct is putting health, safety, and lives at risk.

125. Defendants' unfair conduct is interfering with Lilly's ability to conduct its business. As a direct and proximate result of Defendants' unfair business practices, Lilly is suffering immediate and continuing, competitive, irreparable injury for which no adequate remedy at law exists.

126. As a direct and proximate result of Defendants' deceptive and unfair business practices, Defendants has obtained an unfair and illegal business advantage, thereby benefitting and profiting from sales it made as a result of goodwill associated with Lilly's MOUNJARO® and ZEPBOUND® tirzepatide

medicines. Lilly has suffered and will continue to suffer monetary damages that can be measured and quantified as well as discernible competitive injury by the loss of goodwill.

127. Lilly is entitled to all remedies available under the California Unfair Competition Law, including injunctive relief, restitution, and attorneys' fees.

THIRD CAUSE OF ACTION
False Advertising
in Violation of the California Unfair Competition Law,
Cal. Bus. & Prof. Code §§ 17500 *et. seq.*

(Against Fella)

128. Lilly repeats and realleges each and every allegation above as if fully set forth herein.

129. The California Unfair Competition Law prohibits "any unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue, or misleading advertising."

130. Fella's deceptive, untrue, and misleading advertising violates Cal. Bus. & Prof. Code § 17500.

131. Fella misleads California consumers through its marketing and selling of compounded tirzepatide drugs. Fella's advertisements are untrue or misleading as to its compounded tirzepatide products, as they create the false impression that Fella's compounded oral and injectable tirzepatide (i) are safe and effective; (ii) are FDA approved; (iii) are supported by clinical studies; (iv) are comparable to or superior to Lilly's FDA approved medicines; and (v) have been personalized to fit patients' unique needs.

132. Fella's untrue statements are misleading because, among other things, they steer patients seeking weight loss treatments away from obtaining safe, effective, and FDA-approved treatments. Fella's unlawful conduct is putting health, safety, and lives at risk.

133. Fella's consumer-oriented conduct actually or has likely misled consumers and is likely to continue to mislead them.

134. Fella knew or should have known that their misleading conduct actually or has likely misled consumers and is likely to continue to mislead them.

135. Fella's false advertising conduct is interfering with Lilly's ability to conduct its business. As a direct and proximate result of Fella's false and misleading statements, Lilly is suffering immediate and continuing, competitive, irreparable injury for which there is no adequate remedy at law.

136. As a direct and proximate result of Fella's false advertising practices, Fella has unfairly benefitted and profited from sales it made as a result of goodwill associated with Lilly's MOUNJARO® and ZEPBOUND® tirzepatide medicines. Lilly has suffered and will continue to suffer monetary damages that can be measured and quantified as well as discernible competitive injury by the loss of goodwill.

137. Lilly is entitled to all remedies available under the California Unfair Competition Law, including injunctive relief, restitution, and attorneys' fees.

FOURTH CAUSE OF ACTION
False or Misleading Advertising and Promotion in Violation of 15 U.S.C. § 1125(a)(1)(B)

(Against Fella)

138. Lilly repeats and realleges each and every allegation above as if fully set forth herein.

139. Fella's commercial advertising claims described herein are false and misleading in violation of Section 43(a)(1)(B) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B).

140. Fella has made materially false and misleading statements to sell its compounded tirzepatide products, including by creating the false impression that Fella's compounded tirzepatide (i) are safe and effective; (ii) are FDA approved; (iii) are supported by clinical studies; (iv) are comparable to or superior to Lilly's FDA approved medicines; and (v) have been personalized to fit patients' unique needs.

141. These statements have influenced and are likely to continue to influence consumers' purchasing decisions—specifically, decisions to purchase Fella's oral tirzepatide products instead of Lilly's FDA-approved medicines.

142. Fella's false and deceptive statements and business practices actually deceive or have the tendency to deceive consumers.

143. Fella has caused its false and deceptive statements to enter interstate trade or commerce.

144. As a direct and proximate result of Fella's false and deceptive statements and practices, Lilly is suffering immediate and continuing irreparable injury for which there is no adequate remedy at law.

145. As a direct and proximate result of Fella's false and deceptive campaign, Lilly has suffered and will continue to suffer significant monetary damages and discernible competitive injury by the loss of goodwill.

146. Given Defendants' conduct, this is an exceptional case under 15 U.S.C. § 1117.

147. Lilly is entitled to injunctive relief as well as monetary damages, and other remedies provided by Sections 1116, 1117, and 1118, including Fella's profits, treble damages, reasonable attorneys' fees, costs, and prejudgment interest.

FIFTH CAUSE OF ACTION
Civil Conspiracy

(Against All Defendants)

148. Lilly repeats and realleges the allegations in the paragraphs above as if fully set forth herein.

149. Defendants entered into a common plan and agreement and acted in concert to unlawfully prescribe and sell compounded tirzepatide drugs in violation of the California Unfair Competition Law and the Lanham Act.

150. Defendants participated in an unlawful scheme to prescribe and sell compounded tirzepatide including Cartwright's overlapping control of Fella and Fella Medical Group, through non-physician influence and control over prescribing decisions, and by modifying the formulation, dosage and titration schedule of compounded drugs prescribed to Defendants' customers.

151. As a direct and proximate result of Defendants' unlawful practices, Lilly has suffered and will continue to suffer significant monetary damages and discernible competitive injury by the loss of goodwill.

152. As a result of Defendants' conspiracy, Lilly has been damaged in an amount to be determined at trial.

JURY DEMAND

Lilly hereby demands a jury trial for all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Lilly prays that this Court enter judgment in Lilly's favor on Lilly's claim for relief set forth above and award Lilly relief including, but not limited to, the following:

153. An order declaring that Fella:

i. Engaged in unfair and unlawful trade practices, including the unlawful corporate practice of medicine, corporate control of prescription practices, and unlawful prescription and sale of oral and injectable tirzepatide in violation of the California Unfair Competition Law, Cal. Bus. & Prof. Code §§ 17200 *et seq.*;

ii. Engaged in false advertising in violation of the California Unfair Competition Law, Cal. Bus. & Prof. Code §§ 17500 *et seq.*;

iii. Engaged in false and deceptive advertising and promotion, in violation of 15 U.S.C. § 1125(a)(1)(B); and

iv. Fella, Fella Medical Group, P.A., and Fella Medical Group, P.C. engaged in a conspiracy to unlawfully prescribe and sell compounded tirzepatide drugs.

154. An injunction preliminarily and then permanently enjoining and restraining Fella and its officers, agents, employees, and attorneys and all persons acting in concert or participation with any of them from:

i. Engaging in the corporate practice of medicine and the unlicensed practice of medicine;

ii. Marketing, distributing, dispensing, or otherwise making available to consumers Fella's compounded tirzepatide products;

iii. Claiming or representing that Fella's compounded oral and injectable tirzepatide is safe and effective, FDA-approved, supported by clinical studies, comparable to or superior to Lilly's FDA-approved medicines, or personalized to fit patients' unique needs;

iv. Engaging in any deceptive acts; and

v. Engaging in the unlicensed practice of medicine.

155. An order requiring Fella and its officers, agents, employees, and attorneys and all persons acting in concert or participation with any of them, to engage in corrective advertising by informing consumers that:

i. Fella's tirzepatide products are not an FDA-approved medication;

ii. Fella's tirzepatide products are not proven safe and effective;

iii. Fella's tirzepatide products have never been studied in clinical trials;

iv. Fella's tirzepatide products do not have any proven therapeutic effect;

v. Fella's tirzepatide products are not comparable or equivalent to any FDA-approved injectable tirzepatide drug product;

vi. Fella's tirzepatide products are not superior to any FDA-approved injectable tirzepatide drug product;

vii. Lilly's clinical testing regarding Lilly's FDA-approved injectable tirzepatide medicines provide no support for the safety, effectiveness, or quality of Fella's oral tirzepatide products.

156. An order directing Fella to file with this Court and serve on Lilly's attorneys, thirty (30) days after the date of entry of any injunction, a report in writing and under oath setting forth in detail the manner and form in which it has complied with the Court's injunction.

157. An order requiring Fella to account for and pay to Lilly any and all profits arising from the foregoing acts of deceptive advertising and business practices pursuant to 15 U.S.C. §1117, Cal. Bus. & Prof. Code § 17200, and other applicable laws.

158. An order requiring Fella to pay Lilly compensatory damages in an amount as yet undetermined caused by the false or misleading advertising and business practices and trebling such compensatory damages for payment to Lilly in accordance with 15 U.S.C. §1117, Cal. Bus. & Prof. Code § 17200, and other applicable laws.

159. An order for pre-judgment and post-judgment interest on all damages.

160. A finding that Fella's actions are exceptional under 15 U.S.C. § 1117.

161. An order requiring Fella to pay Lilly's costs and attorneys' fees in this action pursuant to 15 U.S.C. §1117, Cal. Bus. & Prof. Code § 17200, and any other applicable provision of law.

162. Other relief as the Court may deem appropriate.

Dated: April 23, 2025

Respectfully submitted,

/s/ Yungmoon Chang

Yungmoon Chang

James F. Hurst (*pro hac vice* forthcoming)
Diana M. Watral (*pro hac vice* forthcoming
Ryan Moorman (*pro hac vice* forthcoming)
Robin McCue (*pro hac vice* forthcoming)
James R.P. Hileman (*pro hac vice* forthcoming)
KIRKLAND & ELLIS LLP
333 West Wolf Point Plaza
Chicago, Illinois 60654
Telephone: (312) 862-2000
james.hurst@kirkland.com
diana.watral@kirkland.com
ryan.moorman@kirkland.com
robin.mccue@kirkland.com
jhileman@kirkland.com

Joshua L. Simmons (*pro hac vice* forthcoming)
Jeanna M. Wacker (*pro hac vice* forthcoming)
KIRKLAND & ELLIS LLP
601 Lexington Avenue
New York, New York 10022
Telephone: (212) 446-4800
joshua.simmons@kirkland.com
jeanna.wacker@kirkland.com

Yungmoon Chang (S.B.N. 311673)
KIRKLAND & ELLIS LLP
2049 Century Park East
Suite 3700
Los Angeles, California 90067
Telephone: (310) 552 4200
yungmoon.chang@kirkland.com

Attorneys for Plaintiff
ELI LILLY AND COMPANY